UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

June 20, 2011

MEMORANDUM

Subject: Efficacy Review for Dagwood; EPA File Symbol 67619-EL; DP Barcode: D388280.

From: Ibrahim Laniyan, Ph.D.
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Antimicrobials Division (7510P)

Applicant: Clorox Professional Products Company
1221 Broadway
Oakland, CA 94612

Formulation from the Label:

Active Ingredient	% by wt.
Hydrogen Peroxide	1.4 %
Other ingredients	98.6 %
Total	100.0 %

I. BACKGROUND

The product, Dagwood (EPA File Symbol 67619-EL), is a new towelette product. The applicant requested to register the product for use as a disinfectant (bactericide, fungicide, tuberculocide) and deodorizer on hard, non-porous surfaces in household, commercial, institutional, industrial, food processing, food service, animal care, and hospital or medical environments. The label states that the product is an effective bactericide, fungicide, and virucide in the presence of organic soil (5% blood serum). Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated February 10, 2011), EPA Form 8570-4 (Confidential Statement of Formula) for the basic formulation and three alternative formulations, thirty nine studies (MRID 483832-02 through 483832-40), Statements of No Data Confidentiality Claims for all thirty nine studies, and the proposed label.

Note: The laboratory reports describe studies conducted for the product, Dagwood F2010.0128. The applicant's letter to EPA (dated February 10, 2011) states that the tested product, Dagwood F2010.0128, is the basic formulation of the product, Dagwood, which is the subject of this efficacy report.

Note: EPA Form 8570-4 (Confidential Statement of Formula) contains Confidential Business Information. Data or information claimed by the applicant to be FIFRA confidential has not been included in this report.

II. USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, including: animal equipment found in housing facilities, appliance exteriors, basins, bathtubs, bed frames, booster chairs, cabinets, cages, carts, cases, ceilings, cellular phones, chairs, changing tables, computer keyboards, computers, coolers, countertops, crates, desks, diaper pails, dish racks, door handles, door knobs, drain boards, elevator buttons, exercise equipment, exhaust fans, faucet handles, feeding and watering equipment, fixtures, floors, furniture, garbage bins, garbage cans, grocery carts, gymnastic equipment, hampers, hospital equipment (e.g., bedpans, gurneys, paddles, scales, stretchers, wheelchairs), hand rails, inflatable plastic and rubber structures, instruments, kennels, lamps, light fixtures, light switches, lockers, mirrors, office machinery, piano keys, playpens, racks, railings, recycling bins, remote controls, seats, shelves, shower curtains, shower stalls, signs, sinks, sports equipment, staplers, strollers, tables, telephones, toilets, tools, towel dispensers, toy boxes, toys, trays, urinals, utensils, vanity tops, wallpaper, walls, window blinds, work benches, and wrestling mats. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: baked enamel, finished hardwood, Formica, glass, glazed ceramic, glazed porcelain, glazed tile, laminated surfaces, linoleum, Marlite, metal (e.g., chrome, plated steel, stainless steel), naugahyde, painted surfaces, plastic, Plexiglas, sealed fiberglass, sealed granite, sealed marble, synthetic marble, and vinyl. Directions on the proposed label provide the following information regarding use of the product as a disinfectant: Wipe surface until completely wet. Allow the product to remain wet for contact times listed on the label (e.g., 5 minutes against *Mycobacterium bovis* BCG; 8 minutes against fungi). Let air dry. For heavily soiled areas, a pre-cleaning is required.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Antimicrobial Products for Use on Hard Surfaces Using Pre-saturated or Impregnated Towelettes: Towelette products represent a unique combination of antimicrobial chemical and applicator, pre-packaged as a unit in fixed proportions. As such, the complete product, as offered for sale, should be tested according to the directions for use to ensure the product's effectiveness in treating hard surfaces. The standard test methods available for hard surface disinfectants and sanitizers, if followed exactly, would not closely simulate the way a towelette product is used. Agency guidelines recommend that a simulated-use test be conducted by modifying the standard test methods. Agency guidelines further recommend that instead of spraying the inoculated surface of the carrier, the product should be tested by wiping the surface of the carrier with the saturated towelette, and then subculturing the slides after a specified holding time. Performance standards of the standard test methods must be met. These Agency standards are presented in EPA Pesticide Assessment Guidelines, Subdivision G, §91-2(h), Pre-saturated or impregnated towelettes; and the April 12, 2001 EPA Memorandum, Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments: The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against *Salmonella enterica* (ATCC 10708; formerly *Salmonella choleraesuis*), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as "disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria): Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using the AOAC Germicidal Spray Products as Disinfectants Method): The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Germicidal Spray Products as Disinfectants Method contains procedures for testing fungicidal activity. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Note: As an interim policy, EPA is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans*. EPA recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until EPA determines that the laboratories are able to achieve consistent carrier counts at the 10^6 level.

Disinfectants for Use as Tuberculocides (Using the AOAC Tuberculocidal Activity of Disinfectants Test Method): Disinfectants may bear additional label claims of effectiveness as tuberculocides when supported by appropriate tuberculocidal effectiveness data. Certain chemical classes (i.e., glutaraldehyde and quaternary ammonium compounds) are required to undergo validation testing in addition to basic testing. Products that are formulated with other chemical groups do not require validation testing. When using the existing or modified AOAC Tuberculocidal Activity Test Methods, 10 carriers for each of 2 samples, representing 2 different product lots, must be tested against *Mycobacterium bovis* BCG (a member of the *Mycobacterium tuberculosis* species complex). Killing on all carriers/slides as demonstrated in Modified Proskauer-Beck Broth, and no growth in any of the inoculated tubes of 2 additional media (i.e., Middlebrook 7H9 Broth Difco B, Kirchners Medium, and/or TB Broth Base) is required.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Virucides – Novel Virus Protocol Standards: To ensure that a virus protocol has been adequately validated, data should be provided from at least 2 independent laboratories for each product tested (i.e., 2 product lots per laboratory).

Supplemental Claims: An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 483832-02 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Salmonella enterica* (ATCC 10708)" for Dagwood F2010.0128, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – August 20, 2010. Project Number A09770.

This study was conducted against *Salmonella enterica* (ATCC 10708). Three lots (Lot Nos. 10ACE5, 10ACE6, and 10ACE1) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18062310.TOW.3 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. At least one of the product lots tested (i.e., Lot No. 10ACE1) was at least 60 days old at the time of testing. Fetal bovine serum was added to the

culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 40 minutes at 35-37°C at 41% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 20°C at 56% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation (all three product lots).

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

2. MRID 483832-03 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Pseudomonas aeruginosa* (ATCC 15442)" for Dagwood F2010.0128, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – August 19, 2010. Project Number A09769.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot Nos. 10ACE5, 10ACE6, and 10ACE1) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18062310.TOW.2 (copy provided). At least one of the product lots tested (i.e., Lot No. 10ACE1) was at least 60 days old at the time of testing. The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 35 minutes at 35-37°C at 43% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 20°C at 61% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. [It is unknown whether tubes containing neutralizer were shaken thoroughly after addition of the carriers, as specified in the AOAC method.] All subcultures were incubated for 48±4 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation (all three product lots).

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

3. MRID 483832-04 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Staphylococcus aureus* (ATCC 6538)" for Dagwood F2010.0128, by Joshua Luedtke. Study conducted at ATS Labs.Study completion date – November 8, 2010. Project Number A09893.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. 10ACE5, 10ACE6, and 10ACE1) of the product, Dagwood F2010.0128, were tested using

ATS Laboratory Protocol No. CX18072310.TOW (copy provided). At least one of the product lots tested (i.e., Lot No. 10ACE1) was at least 60 days old at the time of testing. The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 30 minutes at 35-37°C at 42-43% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 45 seconds at 20°C at 54% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

4. MRID 483832-05 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Acinetobacter baumannii* (ATCC 19606)" for Dagwood F2010.0128, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – November 17, 2010. Project Number A10481.

This study was conducted against *Acinetobacter baumannii* (ATCC 19606). Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18091610.TOW (copy provided). The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 30 minutes at 35-37°C at 27.7-28.9% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 45 seconds at 21°C at 23% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C. The subcultures were stored for 2 days at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

5. MRID 483832-06 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: Vancomycin Resistant *Enterococcus faecalis* - VRE (ATCC 51575)" for Dagwood F2010.0128, by Lynsey Wieland. Study conducted at ATS Labs. Study completion date – October 6, 2010. Project Number A10061.

This study was conducted against Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575). Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18070210.TOW.3 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. Testing was conducted on August 23, 2010 and September 16, 2010. Fetal bovine serum was added to each culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread

over a 1 inch x 1 inch area of each carrier. For testing conducted on August 23, 2010, the carriers were dried for 30 minutes at 25-30°C at 69% relative humidity. For testing conducted on September 16, 2010, the carriers were dried for 40 minutes at 25-30°C at 63-65% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. For testing conducted on August 23, 2010, the carriers were allowed to remain wet for 30 seconds at 20°C at 65% relative humidity. For testing conducted on September 16, 2010, the carriers were allowed to remain wet for 30 seconds at 19°C at 44% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. For testing conducted on August 23, 2010, all subcultures were incubated for 45.75 hours at 35-37°C. For testing conducted on September 16, 2010, all subcultures were incubated for 46.5 hours at 35-37°C. The subcultures from testing conducted on September 16, 2010 were stored for 2 days at 2-8°C prior to examination. Following incubation or incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, neutralization confirmation, and antibiotic resistance.

Note: Testing conducted on August 23, 2010 against Vancomycin Resistant *Enterococcus faecalis* at a 30-second exposure time showed growth in the subculture of 1 of the 10 carriers for Lot No. 10ACE5. Testing was repeated to test for false positives.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

Note: Antibiotic resistance of Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575) was verified on a representative culture. The laboratory performed a Kirby Bauer Susceptibility assay. *Staphylococcus aureus* (ATCC 25923) was the control organism. The measured zone of inhibition (i.e., 11 mm for testing conducted on August 23, 2010; 6 mm for testing conducted on September 16, 2010) confirmed antibiotic resistance of Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575) to vancomycin. See page 9 and Table 5 of the laboratory report.

6. MRID 483832-07 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Escherichia coli* (ATCC 11229)" for Dagwood F2010.0128, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – September 7, 2010. Project Number A09983.

This study was conducted against *Escherichia coli* (ATCC 11229). Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18070210.TOW.5 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 30 minutes at 35-37°C at 43-45% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 23°C at 63% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 44 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

7. MRID 483832-08 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Escherichia coli* O157:H7 (ATCC 35150)" for Dagwood F2010.0128, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – September 7, 2010. Project Number A09984.

This study was conducted against *Escherichia coli* O157:H7 (ATCC 35150). Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18070210.TOW.6 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 30 minutes at 35-37°C at 43-45% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 23°C at 63% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 44 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

8. MRID 483832-09 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Escherichia coli* with extended beta-lactamase resistance (ATCC BAA-196)" for Dagwood F2010.0128, by Becky Lien. Study conducted at ATS Labs. Study completion date – September 8, 2010. Amended report date – September 16, 2010. Project Number A09998.

This study was conducted against *Escherichia coli* with extended beta-lactamase resistance (ATCC BAA-196). Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18070210.TOW.4 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 30 minutes at 35-37°C at 41-42% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 23°C at 64% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 44 hours at 35-37°C. The subcultures were stored for 2 days at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, neutralization confirmation, and antibiotic resistance.

Note: The antimicrobial susceptibility pattern of *Escherichia coli* with extended beta-lactamase resistance (ATCC BAA-196) was verified on a representative culture. The laboratory performed an AB BIODISK E test Method assay. An E test strip containing Cefotaxime (CT) and Cefotaxime + Clavulanic acid (CTL) and an E test strip containing Ceftazidime (TZ) and

Ceftazidime + Clavulanic acid (TZL) were used. *Escherichia coli* (ATCC 35218) served as the negative control organism. *Klebsiella pneumoniae* (ATCC 700603) served as the positive control organism. The Minimum Inhibitory Concentration (MIC) values were determined. The MIC values confirmed the antimicrobial susceptibility pattern *Escherichia coli* with extended beta-lactamase resistance (ATCC BAA-196). See page 9 and Tables 5-7 of the laboratory report.

Note: The initial laboratory report was amended to correct the name of the positive control organism, and to update the Table of Contents and all page headings.

9. MRID 483832-10 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Klebsiella pneumoniae* Carbapenem Resistant (BAA-1705)" for Dagwood F2010.0128, by Anne Stemper. Study conducted at ATS Labs. Study completion date – September 14, 2010. Project Number A09997.

This study was conducted against *Klebsiella pneumoniae* Carbapenem Resistant (BAA-1705). Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18070810.TOW.3 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 30 minutes at 35-37°C at 41-43% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 23°C at 65% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C. The subcultures were stored for an unspecified time at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, neutralization confirmation, and antibiotic resistance.

Note: Antibiotic resistance of *Klebsiella pneumoniae* Carbapenem Resistant (BAA-1705) was verified on a representative culture. The laboratory performed a Modified Hodge Test to confirm that the test organism produces a carbapenemase and is, therefore, carbapenem resistant. *Klebsiella pneumoniae* (ATCC BAA-1705) was the positive control organism. *Klebsiella pneumoniae* (ATCC BAA-1706) was the negative control organism. The presence of carbapenemase was demonstrated. Thus, antibiotic resistance of *Klebsiella pneumoniae* Carbapenem Resistant (ATCC BAA-1705) to carbapenem was confirmed. See page 9 and Table 5 of the laboratory report.

10. MRID 483832-11 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: Multidrug Resistant *Klebsiella pneumoniae* (ATCC 51503)" for Dagwood F2010.0128, by Anne Stemper. Study conducted at ATS Labs. Study completion date – September 23, 2010. Project Number A09996.

This study was conducted against Multidrug Resistant *Klebsiella pneumoniae* (ATCC 51503). Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18070810.TOW.2 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the

culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 30 minutes at 35-37°C at 42-43% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 23°C at 64% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C. The subcultures were stored for 2 days at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, neutralization confirmation, and antibiotic resistance.

Note: An extended antibiotic resistance profile of Multidrug Resistant *Klebsiella pneumoniae* (ATCC 51503) was performed. Testing was performed using an organism culture from the day of testing. The testing was performed at the University of Minnesota Physicians Outreach Laboratory in Minneapolis, MN. The testing was not performed under EPA GLP regulations. The minimum inhibitory concentrations confirmed antibiotic resistance of Multidrug Resistant *Klebsiella pneumoniae* (ATCC 51503) to ampicillin, ampicillin/sulbactam, cefazolin, cefepime, ceftazidime, ceftriaxone, gentamicin, piperacillin/tazo, and trimethoprim/sulfa. See page 9 and Attachment I of the laboratory report.

11. MRID 483832-12 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Klebsiella pneumoniae* with extended beta-lactamase resistance (ATCC 700603)" for Dagwood F2010.0128, by Becky Lien. Study conducted at ATS Labs. Study completion date – September 9, 2010. Project Number A10006.

This study was conducted against *Klebsiella pneumoniae* with extended beta-lactamase resistance (ATCC 700603). Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18070810.TOW.1 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 30 minutes at 35-37°C at 42% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 20°C at 52% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 45.5 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, neutralization confirmation, and antibiotic resistance.

Note: The antimicrobial susceptibility pattern of *Klebsiella pneumoniae* with extended beta-lactamase resistance (ATCC 700603) was verified on a representative culture. The laboratory performed an AB BIODISK E test Method assay. An E test strip containing Cefotaxime (CT) and Cefotaxime + Clavulanic acid (CTL) and an E test strip containing Ceftazidime (TZ) and Ceftazidime + Clavulanic acid (TZL) were used. *Escherichia coli* (ATCC 35218) served as the negative control organism. *Klebsiella pneumoniae* (ATCC 700603) served as the positive

control organism. The Minimum Inhibitory Concentration (MIC) values were determined. The MIC values confirmed the antimicrobial susceptibility pattern of *Klebsiella pneumoniae* with extended beta-lactamase resistance (ATCC 700603). See page 9 and Tables 5-7 of the laboratory report.

12. MRID 483832-13 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Enterobacter aerogenes* (ATCC 13048)" for Dagwood F2010.0128, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – August 30, 2010. Project Number A09982.

This study was conducted against *Enterobacter aerogenes* (ATCC 13048). Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18070210.TOW.2 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 30 minutes at 35-37°C at 38-43% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 23°C at 62% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 48±4 hours at 25-30°C. The subcultures were stored for 2 days at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

13. MRID 483832-14 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Stenotrophomonas maltophilia* (ATCC 25596)" for Dagwood F2010.0128, by Matthew Sathe. Study conducted at ATS Labs. Study completion date – September 17, 2010. Project Number A10089.

This study was conducted against *Stenotrophomonas maltophilia* (ATCC 25596). Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18071310.TOW.4 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a ~52.75 hour old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 30 minutes at 35-37°C at 41-44% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 21°C at 64% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. Carriers were transferred from the primary subcultures into individual secondary subcultures containing 40 mL of tryptic soy broth at least 30 minutes following the first transfer. All subcultures were incubated for 44 hours at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

14. MRID 483832-15 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Streptococcus pyogenes* (ATCC 19615)" for Dagwood F2010.0128, by Matthew Sathe. Study conducted at ATS Labs. Study completion date – September 30, 2010. Project Number A10090.

This study was conducted against *Streptococcus pyogenes* (ATCC 19615). Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18071310.TOW.6 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a ~51 hour old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 30 minutes at 25-30°C at 62% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 20°C at 46% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Brain Heart Infusion Broth with 0.01% Catalase to neutralize. All subcultures were incubated for 44.25 hours at 35-37°C in CO_2. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

15. MRID 483832-16 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592)" for Dagwood F2010.0128, by Lynsey Wieland. Study conducted at ATS Labs. Study completion date – October 7, 2010. Project Number A10208.

This study was conducted against Methicillin Resistant *Staphylococcus aureus* (ATCC 33592). Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18090110.TOW.1 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 30 minutes at 35-37°C at 42-48% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 45 seconds at 21°C at 50% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 49 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, neutralization confirmation, and antibiotic resistance.

Note: Antibiotic resistance of Methicillin Resistant *Staphylococcus aureus* (ATCC 33592) was verified on a representative culture. The laboratory performed a Kirby Bauer Susceptibility assay. *Staphylococcus aureus* (ATCC 25923) was the control organism. The measured zone of inhibition (i.e., 6 mm) confirmed antibiotic resistance of Methicillin Resistant *Staphylococcus aureus* (ATCC 33592) to oxacillin. See page 9 and Table 5 of the laboratory report.

16. MRID 483832-17 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: Methicillin Resistant *Staphylococcus aureus* - MRSA Hospital Acquired (ATCC 33591)" for Dagwood F2010.0128, by Lynsey Wieland. Study conducted at ATS Labs. Study completion date – October 8, 2010. Project Number A10209.

This study was conducted against Methicillin Resistant *Staphylococcus aureus* Hospital Acquired (ATCC 33591). Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18090110.TOW.2 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 40 minutes at 35-37°C at 38-42% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. he carriers were allowed to remain wet for 45 seconds at 21°C at 48% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 48.25 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, neutralization confirmation, and antibiotic resistance.

Note: Antibiotic resistance of Methicillin Resistant *Staphylococcus aureus* Hospital Acquired (ATCC 33591) was verified on a representative culture. The laboratory performed a Kirby Bauer Susceptibility assay. *Staphylococcus aureus* (ATCC 25923) was the control organism. The measured zone of inhibition (i.e., 6 mm) confirmed antibiotic resistance of Methicillin Resistant *Staphylococcus aureus* Hospital Acquired (ATCC 33591) to oxacillin. See page 9 and Table 5 of the laboratory report.

17. MRID 483832-18 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: Community Acquired Methicillin Resistant *Staphylococcus aureus* - CA-MRSA (NARSA NRS384) (Genotype USA300)" for Dagwood F2010.0128, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – October 6, 2010. Project Number A10088.

This study was conducted against Community Acquired Methicillin Resistant *Staphylococcus aureus* (NARSA NRS384) (Genotype USA300; obtained from the NARSA Contracts Administrator, Focus Technologies, Inc., Herndon, VA). Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18071310.TOW.3 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. Testing was conducted on August 26, 2010 and September 16, 2010. Fetal bovine serum was added to each culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 48-54 hour old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. For testing conducted on August 26, 2010, the carriers were dried for 30 minutes at 35-37°C at 43-44% relative humidity. For testing conducted on September 16, 2010, the carriers were dried for 30 minutes at 35-37°C at 45.86-47.46% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 45 seconds at 19-21°C at 44-55% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Letheen Broth

with 0.1% sodium thiosulfate and 0.01% Catalase to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C. The subcultures were stored for 2 days at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, neutralization confirmation, and antibiotic resistance.

Note: Testing conducted on August 26, 2010 against Community Acquired Methicillin Resistant *Staphylococcus aureus* (NARSA NRS384) (Genotype USA300) at a 45-second exposure time showed growth in the subculture of 1 of the 10 carriers for Lot No. 10ACE6. Testing was repeated to test for false positives.

Note: Antibiotic resistance of Community Acquired Methicillin Resistant *Staphylococcus aureus* (NARSA NRS384) (Genotype USA300) was verified on a representative culture. The laboratory performed a Kirby Bauer Susceptibility assay. *Staphylococcus aureus* (ATCC 25923) was the control organism. The measured zone of inhibition (i.e., 6 mm for testing conducted on August 26, 2010; 6 mm for testing conducted on September 16, 2010) confirmed antibiotic resistance of Community Acquired Methicillin Resistant *Staphylococcus aureus* (NARSA NRS384) (Genotype USA300) to oxacillin. See page 9 and Table 5 of the laboratory report.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

18. MRID 483832-19 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Streptococcus pneumoniae* – Penicillin Resistant (ATCC 700677)" for Dagwood F2010.0128, by Matthew Sathe. Study conducted at ATS Labs. Study completion date – September 23, 2010. Project Number A10062.

This study was conducted against *Streptococcus pneumoniae* - Penicillin Resistant (ATCC 700677). Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18071310.TOW5 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 4 day old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 30 minutes at 25-30°C at 67-68% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 30 seconds at 20°C at 51% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Brain Heart Infusion with 0.01% Catalase to neutralize. All subcultures were incubated for 44 hours at 35-37°C in CO_2. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, neutralization confirmation, and antibiotic resistance.

Note: Antibiotic resistance of *Streptococcus pneumoniae* - Penicillin Resistant (ATCC 700677) was verified on a representative culture. The laboratory performed an E test assay. *Staphylococcus pneumoniae* (ATCC 49619) was the control organism. The Minimum Inhibitory Concentration (MIC) value was determined. The MIC value confirmed antibiotic resistance of *Streptococcus pneumoniae* - Penicillin Resistant (ATCC 700677) to benzylpenicillin. See page 9 and Table 5 of the laboratory report.

19. MRID 483832-20 "AOAC Tuberculocidal Activity of Disinfectant Towelette Products," Test Organism: *Mycobacterium bovis* BCG, for Dagwood F2010.0128, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – October 25, 2010. Project Number A09772.

This study was conducted against *Mycobacterium bovis* BCG (obtained from Organon Teknika Corporation, Durham, NC). Three lots (Lot Nos. 10ACE5, 10ACE6, and 10ACE1) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18062310.TB.2 (copy provided). At least one of the product lots tested (i.e., Lot No. 10ACE1) was at least 60 days old at the time of testing. The product was received ready-to-use, as a pre-saturated towelette. The stock culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 24 day old suspension of the test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 30 minutes at 35-37°C at 44% humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 5 minutes at 22.9°C at 48.4% relative humidity. Following exposure, the carriers were transferred to individual tubes of 40 mL of Letheen Broth with 0.1% sodium thiosulfate and 0.01% Catalase. The carriers were transferred to individual tubes containing 40 mL of Middlebrook 7H9 Broth. From each tube of neutralizer, 2.0 mL were cultured to tubes containing 20 mL of Modified Proskauer-Beck Medium and 2.0 mL were cultured to tubes containing 20 mL of Kirchner's Medium. All tubes used for secondary transfers were incubated for 30 and 60 days at 35-37°C under aerobic conditions. The tubes were incubated for an additional 30 days because no growth was observed after 60 days. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for initial suspension population, carrier population, purity, sterility, viability, and neutralization confirmation.

20. MRID 483832-21 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Trichophyton mentagrophytes* (ATCC 9533)" for Dagwood F2010.0128, by Becky Lien. Study conducted at ATS Labs. Study completion date – November 8, 2010. Project Number A10345.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Three lots (Lot Nos. 10ACE5, 10ACE6, and 10ACE1) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18092810.FTOW.1 (copy provided). At least one of the product lots tested (i.e., Lot No. 10ACE1) was at least 60 days old at the time of testing. The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 10 day old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 30 minutes at 35-37°C at 34.42-38.24% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 7.5 minutes at 22°C at 40% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Sabouraud Dextrose Broth with 0.07% Lecithin, 0.5% Tween 80, and 0.01% Catalase to neutralize. Carriers were transferred from primary subculture jars into individual secondary subculture jars containing 40 mL of Sabouraud Dextrose Broth with 0.07% Lecithin and 0.5% Tween 80 at least 30 minutes following the first transfer. All subcultures were incubated for 10 days at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth.

Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

21. MRID 483832-22 "Pre-Saturated Towelettes for Hard Surface Disinfection, Test Organism: *Candida albicans* (ATCC 10231)" for Dagwood F2010.0128, by Becky Lien. Study conducted at ATS Labs. Study completion date – November 8, 2010. Project Number A10347.

This study was conducted against *Candida albicans* (ATCC 10231). Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested using ATS Laboratory Protocol No. CX18092810.FTOW.3 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers (3 inch x 1 inch) per product lot were inoculated with 10.0 µL of a 2 day old suspension of test organism. Inoculum was uniformly spread over a 1 inch x 1 inch area of each carrier. The carriers were dried for 30 minutes at 25-30°C at 60% relative humidity. Each carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat 10 carriers. A different section of towelette was used to wipe each carrier. The carriers were allowed to remain wet for 7.5 minutes at 22.2°C at 42.9% relative humidity. Following the exposure period, individual carriers were transferred to 40 mL of Sabouraud Dextrose Broth with 0.07% Lecithin, 0.5% Tween 80, and 0.01% Catalase to neutralize. Carriers were transferred from primary subculture jars into individual secondary subculture jars containing 40 mL of Sabouraud Dextrose Broth with 0.07% Lecithin and 0.5% Tween 80 at least 30 minutes following the first transfer. All subcultures were incubated for 44.25 hours at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

22. MRID 483832-23 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces, Virus: Cytomegalovirus, Strain AD-169, ATCC VR-538" for Dagwood F2010.0128, by Shanen Conway. Study conducted at ATS Labs. Study completion date – December 6, 2010. Project Number A09981.

This study was conducted against Cytomegalovirus (Strain AD-169; ATCC VR-538), using MRC-5 cells (human embryonic lung cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested according to ATS Labs Protocol No. CX18070810.CMV.2 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~8 cm x 8 cm) on the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 40% relative humidity. Each carrier was divided into three sections for treatment. Each section of the carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. Overlapping of section wiping was minimal. A different section of towelette was used to wipe each section of the carrier. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 30 seconds at 20.0°C. Following exposure, 2.0 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents ($10^{-1.3}$ dilutions). Ten-fold serial dilutions were prepared, using Minimum Essential Medium with 10% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Following titration, the $10^{-1.3}$ dilutions were passed through individual Sephadex columns to reduce the cytotoxicity of the test substance to the host system. MRC-5

cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 28 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: The laboratory reported a failed study set up on August 11, 2010. In the study, a recoverable virus titer of at least 10^4 was not achieved. The laboratory did not accept the assay. These data were not used to evaluate efficacy of the product. Testing was repeated on October 19, 2010. See page 8 and Attachment I of the laboratory report.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

23. MRID 483832-24 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus" for Dagwood F2010.0128, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – November 10, 2010. Project Number A09892.

This study, under the direction of Study Director Mary J. Miller, was conducted against Duck hepatitis B virus (Strain 7/31/07; obtained from HepadnaVirus Testing, Inc., Palo Alto, CA), using primary duck hepatocytes (cultures prepared by Valley Research Institute personnel using hatchling ducks received from Metzer Farms) as the host system. Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested according to ATS Labs Protocol No. CX18071310.DHBV.4 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained 100% duck serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~8 cm x 8 cm) on the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 30 minutes at 20.0°C at 40% relative humidity. Two replicates per product lot were tested. For each lot of product, individual carriers were wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat two carriers. The carriers were allowed to remain wet for 30 seconds at 20.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Leibovitz L-15 medium with 0.1% glucose, 10 µM dexamethasone, 10 µg/mL insulin, 20 mM HEPES, 10 µg/mL gentamicin, and 100 units/mL penicillin. Primary duck hepatocytes in multi-well culture dishes were inoculated in quadruplicate with 1.0 mL of the dilutions. Test medium was added to sufficiently cover the monolayer during the adsorption period. The cultures were incubated overnight at 36-38°C in a humidified atmosphere of 5-7% CO_2. Post-adsorption, the cultures were re-fed. The cultures were returned to incubation for a total of 9 days at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were re-fed, as necessary. On the final day of incubation, the cultures were scored microscopically for cytotoxicity. An indirect immunofluorescence assay was then performed. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

24. MRID 483832-25 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate

Virus for Human Hepatitis B Virus" for Dagwood F2010.0128, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – November 11, 2010. Project Number A09891.

This confirmatory study, under the direction of Study Director Kelleen Gutzmann, was conducted against Duck hepatitis B virus (Strain 7/31/07; obtained from HepadnaVirus Testing, Inc., Palo Alto, CA), using primary duck hepatocytes (cultures prepared by Valley Research Institute personnel using hatchling ducks received from Metzer Farms) as the host system. One lot (Lot No. 10ACE5) of the product, Dagwood F2010.0128, was tested according to ATS Labs Protocol No. CX18071310.DHBV.3 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained 100% duck serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 30 minutes at 20.0°C at 50% relative humidity. Two replicates were tested. For the single product lot, individual carriers were wiped with a saturated towelette with two wipes back and forth for a total of four passes. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 30 seconds at 20.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Leibovitz L-15 medium with 0.1% glucose, 10 µM dexamethasone, 10 µg/mL insulin, 20 mM HEPES, 10 µg/mL gentamicin, and 100 units/mL penicillin. Primary duck hepatocytes in multi-well culture dishes were inoculated in quadruplicate with 1.0 mL of the dilutions. Test medium was added to sufficiently cover the monolayer during the adsorption period. The cultures were incubated overnight at 36-38°C in a humidified atmosphere of 5-7% CO_2. Post-adsorption, the cultures were re-fed. The cultures were returned to incubation for a total of 9 days at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were re-fed, as necessary. On the final day of incubation, the cultures were scored microscopically for cytotoxicity. An indirect immunofluorescence assay was then performed. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

25. MRID 483832-26 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces Utilizing Bovine Viral Diarrhea Virus as a Surrogate Virus for Human Hepatitis C Virus" for Dagwood F2010.0128, by Shanen Conway. Study conducted at ATS Labs. Study completion date – September 13, 2010. Project Number A10031.

This study, under the direction of Study Director Shanen Conway, was conducted against Bovine viral diarrhea virus (Strain Oregon C24v - genotype 1 cytopathic; obtained from the National Veterinary Services Laboratory, Ames, IA), using BT cells (bovine turbinate cells; ATCC CRL-1390; propagated in-house) as the host system. Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested according to ATS Labs Protocol No. CX18071310.BVD.4 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained 5% horse serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~8 cm x 8 cm) on the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 40% relative humidity. Two replicates per product lot were tested. Each carrier was divided into three sections for treatment. Each section of the carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. Overlapping of section wiping was minimal. A different section of towelette was used to wipe each section of the carrier. One towelette was used to treat two carriers. The carriers were

allowed to remain wet for 30 seconds at 21.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 5% (v/v) non-heat inactivated horse serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. BT cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects (i.e., rounded, dark, with a granular appearance), cytotoxicity, and viability. On the final day of incubation, infectious virus was assayed by a direct immunofluorescence assay to verify the CPE reading. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

26. MRID 483832-27 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces Utilizing Bovine Viral Diarrhea Virus as a Surrogate Virus for Human Hepatitis C Virus - Confirmatory Assay" for Dagwood F2010.0128, by Mary Miller. Study conducted at ATS Labs. Study completion date – September 20, 2010. Project Number A10030.

This confirmatory study, under the direction of Study Director Mary Miller, was conducted against Bovine viral diarrhea virus (Strain Oregon C24v - genotype 1; obtained from the National Veterinary Services Laboratory, Ames, IA), using BT cells (bovine turbinate cells; ATCC CRL-1390; propagated in-house) as the host system. One lot (Lot No. 10ACE5) of the product, Dagwood F2010.0128, was tested according to ATS Labs Protocol No. CX18071310.BVD.3 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained 5% horse serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~8 cm x 8 cm) on the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 50% relative humidity. Two replicates were tested. Each carrier was divided into three sections for treatment. Each section of the carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. Overlapping of section wiping was minimal. A different section of towelette was used to wipe each section of the carrier. One towelette was used to treat two carriers. The carriers were allowed to remain wet for 30 seconds at 21.5°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 5% (v/v) non-heat inactivated horse serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. BT cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects (i.e., rounded, dark, with a granular appearance), cytotoxicity, and viability. On the final day of incubation, infectious virus was assayed by a direct immunofluorescence assay to verify the CPE reading. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

27. MRID 483832-28 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces, Virus: Herpes simplex virus type 1, Strain F(1), ATCC VR-733" for Dagwood F2010.0128, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – November 10, 2010. Project Number A09940.

This study was conducted against Herpes simplex virus type 1 (Strain F(1); ATCC VR-733), using RK cells (rabbit kidney cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested according to ATS Labs Protocol No. CX18070810.HSV1.2 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~8 cm x 8 cm) on the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 50% relative humidity. Each carrier was divided into three sections for treatment. Each section of the carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. Overlapping of section wiping was minimal. A different section of towelette was used to wipe each section of the carrier. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 30 seconds at 20.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 5% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

28. MRID 483832-29 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces, Virus: Herpes simplex virus type 2, Strain G, ATCC VR-734" for Dagwood F2010.0128, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – November 10, 2010. Project Number A09980.

This study was conducted against Herpes simplex virus type 2 (Strain G; ATCC VR-734), using RK cells (rabbit kidney cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested according to ATS Labs Protocol No. CX18070810.HSV2.2 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~8 cm x 8 cm) on the bottoms of separate sterile glass Petri dishes. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 40% relative humidity. Each carrier was divided into three sections for treatment. Each section of the carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. Overlapping of section wiping was minimal. A different section of towelette was used to wipe

each section of the carrier. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 30 seconds at 20.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

29. MRID 483832-30 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces, Virus: Human Immunodeficiency Virus type 1, Strain HTLV-III_B" for Dagwood F2010.0128, by Shanen Conway. Study conducted at ATS Labs. Study completion date – September 23, 2010. Project Number A10009.

This study was conducted against Human immunodeficiency virus type 1 (Strain HTLV-III_B; obtained from Advanced Biotechnologies, Inc., Columbia, MD), using MT-2 cells (human T-cell leukemia cells; obtained through the AIDS Research and Reference Reagent Program, Division of AIDS, NIAID, NIH; maintained in-house) as the host system. Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested according to ATS Labs Protocol No. CX18070810.HIV.2 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~8 cm x 8 cm) on the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C. Each carrier was divided into three sections for treatment. Each section of the carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. Overlapping of section wiping was minimal. A different section of towelette was used to wipe each section of the carrier. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 30 seconds at 20.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in RPMI-1640 with 15% (v/v) heat-inactivated fetal bovine serum, 2.0 mM L-glutamine, and 50 µg/mL gentamicin. MT-2 cells in multi-well culture dishes were inoculated in quadruplicate with 0.2 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 9 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

30. MRID 483832-31 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces, Virus: Avian Influenza A (H5N1) virus, Strain VNH5N1-PR8/CDC-RG CDC #2006719965" for Dagwood F2010.0128, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – September 28, 2010. Project Number A10148.

This study was conducted against Avian influenza A (H5N1) virus (Strain VNH5N1-PR8/CDC-RG CDC #2006719965; obtained from the Centers for Disease Control and Prevention, Atlanta, GA), using RMK cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested according to ATS Labs Protocol No. CX18081210.AFLU (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~8 cm x 8 cm) on the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 21.0°C at 36.6% relative humidity. Each carrier was divided into three sections for treatment. Each section of the carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. Overlapping of section wiping was minimal. A different section of towelette was used to wipe each section of the carrier. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 45 seconds at 21.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

31. MRID 483832-32 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces, Virus: Influenza A (H3N2) virus, Strain Hong Kong, ATCC VR-544" for Dagwood F2010.0128, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – September 3, 2010. Project Number A09951.

This study was conducted against Influenza A (H3N2) virus (Strain Hong Kong; ATCC VR-544), using RMK cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested according to ATS Labs Protocol No. CX18070810.FLUA.4 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~8 cm x 8 cm) on the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 40% relative humidity. Each carrier was divided into three sections for treatment. Each section of the carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. Overlapping of section wiping was minimal. A different section of towelette was used to wipe each section of the carrier. One towelette was used to treat one carrier. The carriers were allowed to remain wet

for 30 seconds at 20.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability.Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

32. MRID 483832-33 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces, Virus: 2009-H1N1 Influenza A virus (Novel H1N1), Strain A/Mexico/4108/2009, CDC #2009712192" for Dagwood F2010.0128, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – September 14, 2010. Project Number A10007.

This study was conducted against 2009-H1N1 Influenza A virus (Novel H1N1) (Strain A/Mexico/4108/2009, CDC #2009712192; obtained from the Centers for Disease Control and Prevention, Atlanta, GA), using RMK cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested according to ATS Labs Protocol No. CX18070810.FLUA.2 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~8 cm x 8 cm) on the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 35.8% relative humidity. Each carrier was divided into three sections for treatment. Each section of the carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. Overlapping of section wiping was minimal. A different section of towelette was used to wipe each section of the carrier. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 30 seconds at 20.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 1% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

33. MRID 483832-34 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces, Virus: Influenza B virus, Strain B/Hong Kong/5/72, ATCC VR-823" for Dagwood F2010.0128, by Shanen Conway. Study conducted at ATS Labs. Study completion date – November 8, 2010. Project Number A09950.

This study was conducted against Influenza B virus (Strain B/Hong Kong/5/72; ATCC VR-823), using RMK cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested according to ATS Labs Protocol No. CX18070810.FLUB.2 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~8 cm x 8 cm) on the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 40% relative humidity. Each carrier was divided into three sections for treatment. Each section of the carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. Overlapping of section wiping was minimal. A different section of towelette was used to wipe each section of the carrier. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 30 seconds at 20.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 1% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

34. MRID 483832-35 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces Utilizing Feline Calicivirus as a Surrogate Virus for Human Norovirus" for Dagwood F2010.0128, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – January 10, 2011. Project Number A10714.

This study, under the direction of Study Director Mary J. Miller, was conducted against Feline calicivirus (Strain F-9; ATCC VR-782), using CRFK cells (Crandel Reese feline kidney cells; ATCC CCL-94; propagated in-house) as the host system. Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested according to ATS Labs Protocol No. CX18121310.FCAL.1 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~8 cm x 8 cm) on the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. Two replicates per product lot were tested. Each carrier was divided into two sections for treatment. Each section of the carrier was wiped with a saturated towelette with two wipes back and forth for a total of

four passes. Overlapping of section wiping was minimal. A different section of towelette was used to wipe each section of the carrier. One towelette was used to treat two carriers. The carriers were allowed to remain wet for 3 minutes at 20.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects (i.e., small, rounding of the cells, with a slight granular look), cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

35. MRID 483832-36 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces Utilizing Feline Calicivirus as a Surrogate Virus for Human Norovirus" for Dagwood F2010.0128, by Shanen Conway. Study conducted at ATS Labs. Study completion date – January 12, 2011. Project Number A10715.

This confirmatory study, under the direction of Study Director Shanen Conway, was conducted against Feline calicivirus (Strain F-9; ATCC VR-782), using CRFK cells (Crandel Reese feline kidney cells; ATCC CCL-94; propagated in-house) as the host system. One lot (Lot No. 10ACE5) of the product, Dagwood F2010.0128, was tested according to ATS Labs Protocol No. CX18121310.FCAL.2 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~8 cm x 8 cm) on the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. Two replicates were tested. Each carrier was divided into two sections for treatment. Each section of the carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. Overlapping of section wiping was minimal. A different section of towelette was used to wipe each section of the carrier. One towelette was used to treat two carriers. The carriers were allowed to remain wet for 3 minutes at 20.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects (i.e., small, rounding of the cells, with a slight granular look), cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

36. MRID 483832-37 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces, Virus: Rhinovirus type 37, Strain 151-1, ATCC VR-1147" for Dagwood F2010.0128, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – November 10, 2010. Project Number A09917.

This study was conducted against Rhinovirus type 37 (Strain 151-1; ATCC VR-1147), using MRC-5 cells (human embryonic lung fibroblasts; ATCC CCL-171; propagated in-house) as the host system. Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested according to ATS Labs Protocol No. CX18070810.R37.2 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~8 cm x 8 cm) on the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 15.0°C at 50% relative humidity. Each carrier was divided into three sections for treatment. Each section of the carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. Overlapping of section wiping was minimal. A different section of towelette was used to wipe each section of the carrier. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 50 seconds at 20.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 10% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. MRC-5 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

37. MRID 483832-38 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces, Virus: Rotavirus, Strain WA" for Dagwood F2010.0128, by Shanen Conway. Study conducted at ATS Labs. Study completion date – November 5, 2010. Project Number A09918.

This study was conducted against Rotavirus (Strain WA; obtained from the University of Ottawa, Ontario, Canada), using MA-104 cells (Rhesus monkey kidney cells; obtained from Diagnostic Hybrids, Inc., Athens, OH; propagated in-house) as the host system. Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested according to ATS Labs Protocol No. CX18070810.ROT.2 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~8 cm x 8 cm) on the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 40% relative humidity. Each carrier was divided into three sections for treatment. Each section of the carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. Overlapping of section wiping was minimal. A different section of towelette was used to wipe each section of the carrier. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 50 seconds at 20.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 0.5 µg/mL trypsin, 2.0 mM L-glutamine, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. MA-104 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The inoculum

was allowed to adsorb for 60 minutes at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were re-fed and returned to incubation at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

38. MRID 483832-39 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces, Virus: Respiratory syncytial virus, Strain Long, ATCC VR-26" for Dagwood F2010.0128, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – November 10, 2010. Project Number A09919.

This study was conducted against Respiratory syncytial virus (Strain Long; ATCC VR-26), using Hep-2 cells (human larynx carcinoma cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lot Nos. 10ACE5 and 10ACE6) of the product, Dagwood F2010.0128, were tested according to ATS Labs Protocol No. CX18070810.RSV.2 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~8 cm x 8 cm) on the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 50% relative humidity. Each carrier was divided into three sections for treatment. Each section of the carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. Overlapping of section wiping was minimal. A different section of towelette was used to wipe each section of the carrier. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 30 seconds at 20.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Eagle's Minimum Essential Medium with 2% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL Fungizone, 10 µg/mL vancomycin, 2 mM L-glutamine, and 10 mM HEPES. Hep-2 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 10 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

39. MRID 483832-40 "Virucidal Efficacy of Pre-Saturated Towelettes for Use on Inanimate Environmental Surfaces, Virus: Human Coronavirus, Strain 229E, ATCC VR-740" for Dagwood F2010.0128, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – September 13, 2010. Project Number A09894.

This study was conducted against Human coronavirus (Strain 229E; ATCC VR-740), using WI-38 cells (human embryonic lung fibroblasts; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lot Nos. 10ACE5 and

10ACE6) of the product, Dagwood F2010.0128, were tested according to ATS Labs Protocol No. CX18070810.COR.2 (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over a defined area (~2 inch x 2 inch) on the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 40% relative humidity. Each carrier was divided into three sections for treatment. Each section of the carrier was wiped with a saturated towelette with two wipes back and forth for a total of four passes. Overlapping of section wiping was minimal. A different section of towelette was used to wipe each section of the carrier. One towelette was used to treat one carrier. The carriers were allowed to remain wet for 30 seconds at 20.0°C. Following exposure, 2.00 mL of test medium was added to each Petri dish. The plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 2% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. WI-38 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 10 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

V. RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Carrier Population (CFU/ carrier)
		Lot No. 10ACE5	Lot No. 10ACE6	Lot No. 10ACE1	
30-Second Exposure Time					
483832-02	*Salmonella enterica* Test Date: 7/19/2010	0/60	0/60	0/60	1.1×10^4
483832-03	*Pseudomonas aeruginosa* Test Date: 7/19/2010	0/60	0/60	0/60	1.67×10^6
483832-06	Vancomycin Resistant *Enterococcus faecalis* Test Date: 8/23/2010 Test Date: 9/16/2010	1/10 0/10	0/10 ---	--- ---	1.08×10^6 3.3×10^6
483832-07	*Escherichia coli* Test Date: 8/11/2010	0/10	0/10	---	5.7×10^6
483832-08	*Escherichia coli* O157:H7 Test Date: 8/11/2010	0/10	0/10	---	8.3×10^5
483832-09	*Escherichia coli* with extended beta-lactamase resistance Test Date: 8/12/2010	0/10	0/10	---	1.30×10^6

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Carrier Population (CFU/ carrier)
		Lot No. 10ACE5	Lot No. 10ACE6	Lot No. 10ACE1	
483832-10	*Klebsiella pneumoniae* Carbapenem Resistant Test Date: 8/12/2010	0/10	0/10	---	1.17×10^6
483832-11	Multidrug Resistant *Klebsiella pneumoniae* Test Date: 8/12/2010	0/10	0/10	---	3.2×10^6
483832-12	*Klebsiella pneumoniae* with extended beta-lactamase resistance Test Date: 8/16/2010	0/10	0/10	---	7.02×10^5
483832-13	*Enterobacter aerogenes* Test Date: 8/12/2010	0/10	0/10	---	1.29×10^7
483832-14	*Stenotrophomonas maltophilia* Test Date: 8/20/2010	1°=0/10 2°=0/10	1°=0/10 2°=0/10	---	2.29×10^7
483832-15	*Streptococcus pyogenes* Test Date: 8/25/2010	0/10	0/10	---	6.1×10^5
483832-19	*Streptococcus pneumoniae* - Penicillin Resistant Test Date: 8/24/2010	0/10	0/10	---	1.11×10^5
45-Second Exposure Time					
483832-04	*Staphylococcus aureus* Test Date: 7/28/2010	0/60	0/60	0/60	3.1×10^6
483832-05	*Acinetobacter baumannii* Test Date: 11/11/2010	0/10	0/10	---	1.71×10^6
483832-16	Methicillin Resistant *Staphylococcus aureus* Test Date: 9/21/2010	0/10	0/10	---	4.8×10^6
483832-17	Methicillin Resistant *Staphylococcus aureus* Hospital Acquired Test Date: 9/21/2010	0/10	0/10	---	2.17×10^7
483832-18	Community Acquired Methicillin Resistant *Staphylococcus aureus* (NARSA NRS384) (Genotype USA300) Test Date: 8/26/2010 Test Date: 9/16/2010	 0/10 ---	 1/10 0/10	 --- ---	 4.4×10^6 4.1×10^6
7.5-Minute Exposure Time					
483832-21	*Trichophyton mentagrophytes* Test Date: 10/8/2010	1°=0/10 2°=0/10	1°=0/10 2°=0/10	1°=0/10 2°=0/10	1.78×10^5
483832-	*Candida albicans*	1°=0/10	1°=0/10	---	2.05×10^5

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Carrier Population (CFU/ carrier)
		Lot No. 10ACE5	Lot No. 10ACE6	Lot No. 10ACE1	
22	Test Date: 10/12/2010	2°=0/10	2°=0/10		

MRID Number	Organism	Results			Dried Virus Count
			Lot No. 10ACE5	Lot No. 10ACE6	
30-Second Exposure Time					
483832-23	Cytomegalovirus	$10^{-1.3}$ dilution	Cytotoxicity	Cytotoxicity	$10^{4.8}$ $TCID_{50}$/0.1 mL
		$10^{-2.3}$ to $10^{-6.3}$ dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/0.1 mL	$\leq 10^{1.8}$	$\leq 10^{1.8}$	
		Log reduction	≥ 3.0 $\log_{10}$	≥ 3.0 $\log_{10}$	
483832-24	Duck hepatitis B virus	10^{-2} to 10^{-4} dilutions	Complete inactivation	Complete inactivation	$10^{5.25}$ and $10^{5.5}$ $TCID_{50}$/1.0mL
		$TCID_{50}$/1.0 mL	$\leq 10^{1.5}$	$\leq 10^{1.5}$	
483832-25	Duck hepatitis B virus	10^{-2} to 10^{-4} dilutions	Complete inactivation	---	$10^{5.25}$ and $10^{5.5}$ $TCID_{50}$/1.0 mL
		$TCID_{50}$/1.0 mL	$\leq 10^{1.5}$	---	
483832-26	Bovine viral diarrhea virus	10^{-1} to 10^{-4} dilutions	Complete inactivation	Complete inactivation	$10^{5.25}$ $TCID_{50}$/0.1mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
483832-27	Bovine viral diarrhea virus	10^{-1} dilution	Cytotoxicity	---	$10^{5.0}$ $TCID_{50}$/0.1 mL
		10^{-2} to 10^{-4} dilutions	Complete inactivation	---	
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$ and $10^{1.5}$	---	
		Log reduction	≥ 4.5 $\log_{10}$ and ≥ 3.5 $\log_{10}$	---	
483832-28	Herpes simplex virus type 1	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{6.0}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
483832-29	Herpes simplex virus type 2	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{5.25}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
483832-30	Human immuno-deficiency virus type 1	10^{-1} dilution	Cytotoxicity	Cytotoxicity	$10^{5.0}$ $TCID_{50}$/0.2 mL
		10^{-2} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/0.2 mL	$\leq 10^{1.5}$	$\leq 10^{1.5}$	
		Log reduction	≥ 3.5 $\log_{10}$	≥ 3.5 $\log_{10}$	
483832-32	Influenza A (H3N2) virus	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{6.25}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
483832-33	2009-H1N1 Influenza A virus (Novel H1N1)	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{5.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	

MRID Number	Organism	Results			Dried Virus Count
			Lot No. 10ACE5	Lot No. 10ACE6	
483832-34	Influenza B virus	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{4.75}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
483832-39	Respiratory syncytial virus	10^{-1} dilution	Cytotoxicity	Complete inactivation	$10^{5.25}$ $TCID_{50}$/0.1 mL
		10^{-2} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/0.1 mL	$\leq 10^{1.5}$	$\leq 10^{0.5}$	
		Log reduction	≥ 3.75 $\log_{10}$	≥ 4.75 $\log_{10}$	
483832-40	Human coronavirus	10^{-1} dilution	Cytotoxicity	Cytotoxicity	$10^{5.5}$ $TCID_{50}$/0.1 mL
		10^{-2} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/0.1 mL	$\leq 10^{1.5}$	$\leq 10^{1.5}$	
		Log reduction	≥ 4.0 $\log_{10}$	≥ 4.0 $\log_{10}$	
45-Second Exposure Time					
483832-31	Avian Influenza A (H5N1) virus	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{4.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
50-Second Exposure Time					
483832-37	Rhinovirus type 37	10^{-1} dilution	Complete inactivation	Cytotoxicity	$10^{4.5}$ $TCID_{50}$/0.1 mL
		10^{-2} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{1.5}$	
		Log reduction	≥ 4.0 $\log_{10}$	≥ 3.0 $\log_{10}$	
483832-38	Rotavirus	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{4.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
3-Minute Exposure Time					
483832-35	Feline calicivirus	10^{-1} to 10^{-4} dilutions	Complete inactivation	Complete inactivation	$10^{7.0}$ and $10^{6.75}$ $TCID_{50}$/0.1mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
483832-36	Feline calicivirus	10^{-1} to 10^{-4} dilutions	Complete inactivation	---	$10^{6.75}$ and $10^{6.5}$ $TCID_{50}$/0.1mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	

MRID Number	Organism	Media	No. Exhibiting Growth/ Total No. Tested		
			Lot No. 10ACE5 90 Days	Lot No. 10ACE6 90 Days	Lot No. 10ACE1 90 Days
5-Minute Exposure Time					
483832-20	*Mycobacterium bovis* BCG Carrier Population: 5.0×10^5 CFU/carrier	Modified Proskauer-Beck Medium[1]	0/10	0/10	0/10
		Middlebrook 7H9 Broth	0/10	0/10	0/10
		Kirchner's Medium[1]	0/10	0/10	0/10

[1]Modified Proskauer-Beck Medium and Kirchner's Medium results could not be used to support product efficacy because neutralization confirmation testing failed to show growth of *Mycobacterium bovis* BCG for both product lots in these media.

VI. CONCLUSIONS

1. The submitted efficacy data **support** the use the product, Dagwood F2010.0128, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for the listed contact times:

Salmonella enterica	30 sec	MRID 483832-02
Pseudomonas aeruginosa	30 sec	MRID 483832-03
Staphylococcus aureus	45 sec	MRID 483832-04
Acinetobacter baumannii	45 sec	MRID 483832-05
Vancomycin Resistant *Enterococcus faecalis*	30 sec	MRID 483832-06
Escherichia coli	30 sec	MRID 483832-07
Escherichia coli O157:H7	30 sec	MRID 483832-08
Escherichia coli with extended beta-lactamase resistance	30 sec	MRID 483832-09
Klebsiella pneumoniae Carbapenem Resistant	30 sec	MRID 483832-10
Multidrug Resistant *Klebsiella pneumoniae*	30 sec	MRID 483832-11
Klebsiella pneumoniae with extended beta-lactamase resistance	30 sec	MRID 483832-12
Enterobacter aerogenes	30 sec	MRID 483832-13
Stenotrophomonas maltophilia	30 sec	MRID 483832-14
Streptococcus pyogenes	30 sec	MRID 483832-15
Methicillin Resistant *Staphylococcus aureus*	45 sec	MRID 483832-16
Methicillin Resistant *Staphylococcus aureus* Hospital Acquired	45 sec	MRID 483832-17
Community Acquired Methicillin Resistant *Staphylococcus aureus* (NARSA NRS384) (Genotype USA300)	45 sec	MRID 483832-18
Streptococcus pneumoniae - Penicillin Resistant	30 sec	MRID 483832-19

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. [Note that repeat testing was conducted on one product lot against Vancomycin Resistant *Enterococcus faecalis* and Community Acquired Methicillin Resistant *Staphylococcus aureus* (NARSA NRS384) (Genotype USA300) to evaluate for false positives.] In testing against *Staphylococcus aureus*, *Salmonella enterica*, and *Pseudomonas aeruginosa*, at least one of the product lots tested was at least 60 days old at the

time of testing. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

2. The submitted efficacy data **support** the use of the product, Dagwood F2010.0128, as a disinfectant with fungicidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a 7.5-minute contact time:

Trichophyton mentagrophytes	MRID 483832-21
Candida albicans	MRID 483832-22

Complete killing was observed in the subcultures of the required number of carriers tested against at least the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

3. The submitted efficacy data **support** the use of the product, Dagwood F2010.0128, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load (a 100% organic soil load against Duck hepatitis B virus) for the listed contact times:

Cytomegalovirus	30 sec	MRID 483832-23
Duck hepatitis B virus	30 sec	MRID 483832-24 and -25
Bovine viral diarrhea virus	30 sec	MRID 483832-26 and -27
Herpes simplex virus type 1	30 sec	MRID 483832-28
Herpes simplex virus type 2	30 sec	MRID 483832-29
Human immunodeficiency virus type 1	30 sec	MRID 483832-30
Avian influenza A (H5N1) virus	45 sec	MRID 483832-31
Influenza A (H3N2) virus	30 sec	MRID 483832-32
2009-H1N1 Influenza A virus (Novel H1N1)	30 sec	MRID 483832-33
Influenza B virus	30 sec	MRID 483832-34
Feline calicivirus	3 min	MRID 483832-35 and -36
Rhinovirus type 37	50 sec	MRID 483832-37
Rotavirus	50 sec	MRID 483832-38
Respiratory syncytial virus	30 sec	MRID 483832-39
Human coronavirus	30 sec	MRID 483832-40

Recoverable virus titers of at least 10^4 were achieved. In studies against Cytomegalovirus, Bovine viral diarrhea virus, Human immunodeficiency virus type 1, Rhinovirus type 37, Respiratory syncytial virus, and Human coronavirus, cytotoxicity was observed in the lowest dilution. Complete inactivation (no growth) was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level. In studies against all other viruses, cytotoxicity was not observed. Complete inactivation (no growth) was indicated in all dilutions tested.

In studies against Duck hepatitis B virus, Bovine viral diarrhea virus, and Feline calicivirus, the initial and confirmatory studies were performed at the same laboratory, but under the direction of different study directors. The confirmatory study tested one product lot, not the standard two product lots.

4. The submitted efficacy data (MRID 483832-20) **support** the use of the product, Dagwood F2010.0128, as a disinfectant with tuberculocidal activity against *Mycobacterium bovis* BCG on hard, non-porous surfaces in the presence of a 5% organic soil load for a 5-minute contact time. Complete killing was observed in the subcultures of the required number of carriers against the required number of product lots. No growth was observed in the subcultures of the two extra media. Neutralization confirmation testing showed positive growth of the microorganism in Middlebrook 7H9 Broth. [Neutralization confirmation testing showed no growth of the microorganism in Modified Proskauer-Beck Medium and Kirchner's Medium.] Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

VII. Label

1. The proposed label claims that the product, Dagwood, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of 5% blood serum for a 30-second contact time:

Carbapenem Resistant *Klebsiella pneumoniae*
Enterobacter aerogenes
Escherichia coli
Escherichia coli O157:H7
Extended spectrum beta lactamase producing *Escherichia coli*
Extended spectrum beta lactamase producing *Klebsiella pneumoniae*
Multidrug Resistant *Klebsiella pneumonia* (**must qualify by listing Drugs**)
Pseudomonas aeruginosa
Salmonella enterica
Stenotrophomonas maltophilia
Penicillin Resistant *Streptococcus pneumoniae*
Streptococcus pyogenes
Vancomycin Resistant *Enterococcus faecalis*

Bovine viral diarrhea virus
Cytomegalovirus
Duck hepatitis B virus
Hepatitis B virus
Hepatitis C virus
Herpes simplex virus type 1
Herpes simplex virus type 2
Human coronavirus
Human immunodeficiency virus type 1
Influenza A virus (H3N2)
Influenza A virus (2009 H1N1)
Influenza B virus
Respiratory syncytial virus

These claims are acceptable as they are supported by the submitted data.

2. The proposed label claims that the product, Dagwood, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of 5% blood serum for a 1-minute contact time:

Acinetobacter baumannii
Community Acquired Methicillin Resistant *Staphylococcus aureus*
Methicillin Resistant *Staphylococcus aureus* (ATCC 33592)
Methicillin Resistant *Staphylococcus aureus* (ATCC 33591)
Staphylococcus aureus

Avian influenza A virus (H5N1)
Rhinovirus
Rotavirus

These claims are acceptable as they are supported by the submitted data.

3. The proposed label claims that the product, Dagwood, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of 5% blood serum for a 3-minute contact time:

Norovirus
Feline calicivirus

These claims are acceptable as they are supported by the submitted data.

4. The proposed label claims that the product, Dagwood, is an effective disinfectant against *Candida albicans* and *Trichophyton mentagrophytes* on hard, non-porous surfaces in the presence of 5% blood serum for an 8-minute contact time. These claims are acceptable as they are supported by the submitted data.

5. The proposed label claims that the product, Dagwood, is an effective tuberculocide on hard, non-porous surfaces in the presence of 5% blood serum for a 5-minute contact time. **These claims are acceptable as they are supported by the submitted data**.

6. The following revisions to the proposed label must be made:

- On page 6 of the proposed label, delete the term "killing" from the allergen claim. The Agency only accepts non-living allergen claims.
- On page 9 of the proposed label, remove the term "fast" and "fast-acting". The Agency has not determined the contact time consistent with this claim.
- On page 9 of the proposed label, remove the claim "99%" as it relates to cold viruses. The Agency does not have a standard represented by this percent reduction.
- On page 9 of the proposed label, remove the acronym "ESKAPE". The Agency has not determined whether this is an acceptable term. Furthermore "*Enterococcus faecium"* not "*faecalis"* is consistent with the ESKAPE nomenclature.
- On page 9 of the proposed label, delete the following claim (and similar claims) as pre-cleaning is required when surfaces are heavily soiled: "**No precleaning required**."
- On page 18 of the proposed label, change "enamel" to read "**baked** enamel." Enamel is a porous surface.
- On page 18 of the proposed label, **delete the following surface: "finished -or-painted woodwork**." Information on page 19 of the proposed label indicates that the product is not recommended for use on "painted wood."