

773-94

02/01/2012

1/13

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



FEB 01 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Patricia Sheehy
Intervet Schering-Plough Animal Health
556 Morris Avenue
Summit, NJ 07091

Dear Ms. Sheehy:

Subject: PRIA Amendment to review submitted efficacy and Companion Animal Safety data to support the following proposed claims: "Flea efficacy demonstrated in global field studies," "Effectively controls fleas in the home environment," "demonstrated effectiveness with dogs with FAD," "May be used with Scalibor Protector Band" and speed of kill claims.
ACTIVYL for Dogs and Puppies
EPA Registration No. 773-94
Your Submission Dated: September 22, 2011
Decision Number 454527

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable provided you make the following changes:

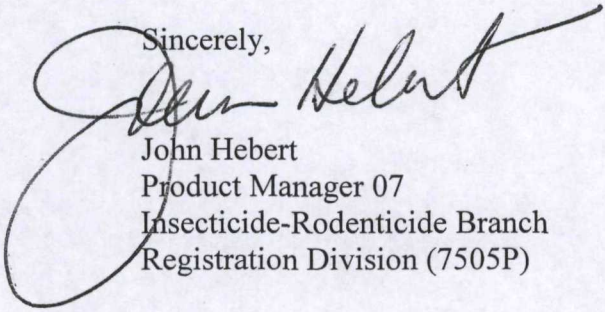
- Page 2: Under "Restrictions," bullet each restriction within the paragraph formatting so that they are easily distinguishable from one another.
- Page 2: Under "Restrictions," for each package size revise "Do not use on puppies under 8 weeks of age and weighing less than XX lbs" with "Do not use on dogs or puppies under 8 weeks of age and weighing less than XX lbs."
- Pages 4: as already noted in the amendment letter dated 12/14/11: revise the sentence that reads "Do not use on dog (male or female) intended for breeding, pregnant or nursing" to read "Do not use on dogs (male or female) intended for breeding, or on dogs that are pregnant or nursing."

The efficacy studies, MRIDs 48598301-05 submitted were reviewed and the findings were summarized in the efficacy memo dated 1/25/12 (A. Metzger). Based on the review, the only claims that are supported are "Effectively controls fleas on dogs in a home environment" and "Starts killing fleas in 8 hours."

The Companion Animal Safety Study submitted, MRID 48598305, was classified as unacceptable in the memo dated 1/9/12 (B.Backus) and the claim "May be used with Scalibor Protector Band" was not supported.

A stamped copy of the labeling is enclosed for your records. Please submit one final printed copy of the labeling before releasing the product for shipment. If you have any questions regarding this label, please contact Autumn Metzger at (703) 305-5314 or metzger.autumn@epa.gov.

Sincerely,



John Hebert
Product Manager 07
Insecticide-Rodenticide Branch
Registration Division (7505P)

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“Master Label”: This master label includes text for different size packages and application rates specific to pet’s age and body weight.

FRONT PANEL

ACTIVYL for Dogs and Puppies

Alternate Brand Names:

- ACTIVYL for Dogs or Puppies
- ACTIVYL Spot-On for Dogs and Puppies
- ACTIVYL Spot-On for Dogs or Puppies
- ACTIVYL for Dogs
- ACTIVYL Spot-On for Dogs

Once-A-Month Topical Flea (Spot-On) (Treatment) (Prevention) (Control) for dogs and puppies 8 weeks and older and weighing

- over (>) (greater than) 4 lb (pounds) (1.8 kg) and (up to) (less than or equal to) 14 lb (pounds) (6.6 kg) ONLY
- over (>) (greater than) 14 lb (pounds) (6.6 g) and (up to) (less than or equal to) 22 lb (pounds) (10 kg) ONLY
- over (>) (greater than) 22 lb (pounds) (10 kg) and (up to)(less than or equal to) 44 lb (pounds) (20 kg) ONLY
- over (>)(greater than) 44 lb (pounds) (20 kg) and (up to)(less than or equal to) 88 lb (pounds) (40 kg) ONLY
- over (>)(greater than) 88 lb (pounds) (40 kg) and (up to)(less than or equal to)132 lb (pounds) (60 kg) ONLY

Active Ingredient:

Indoxacarb:

(S)-methyl 7-chloro-2,5-dihydro-2-[[methoxycarbonyl][4-trifluoromethoxy)phenyl]amino]
-carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate.....19.53%

Other Ingredients:.....80.47%
Total ..100.00%

**KEEP OUT OF REACH OF CHILDREN
WARNING**

SEE BACK PANEL FOR FIRST AID AND ADDITIONAL PRECAUTIONARY STATEMENTS

ACCEPTED
With COMMENTS
In EPA Letter Dated:
FEB 01 2012

**Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:**

773-94

() Bracket text allows for alternative presentations of the same claim.

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BACK PANEL

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

RESTRICTIONS

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON DOGS ONLY. DO NOT USE ON DOGS (MALE OR FEMALE) INTENDED FOR BREEDING, OR ON DOGS THAT ARE PREGNANT OR NURSING. DO NOT USE ON OTHER ANIMALS. DO NOT APPLY MORE THAN ONCE PER MONTH. DO NOT HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL IT IS COMPLETELY DRY.

FOR EXTERNAL USE ON DOGS AND PUPPIES ONLY.

- For 0.51 mL package size: Do not use on puppies under 8 weeks of age and weighing less than 4 lb.
- For 0.77 mL package size: Do not use on puppies under 8 weeks of age and weighing less than 14 lb.
- For 1.54 mL package size: Do not use on puppies under 8 weeks of age and weighing less than 22 lb.
- For 3.08 mL package size: Do not use on puppies under 8 weeks of age and weighing less than 44 lb.
- For 4.62 mL package size: Do not use on puppies under 8 weeks of age and weighing less than 88 lb.

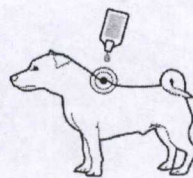
(HOW TO APPLY) Open one foil pouch and remove applicator (tube).



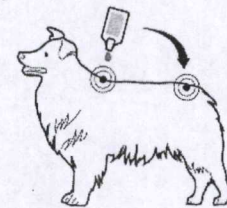
3. Graphics for specific dog sizes represented below – 1 graphic per package size



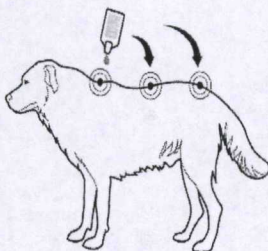
For dogs over 4 lb and up to 14 lb ONLY
(For dogs over 1.8 kg and less than 6.6 kg)
(0.51 mL size only)



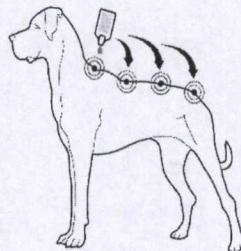
For dogs over 14 lb up to 22 lb ONLY
(For dogs over 6.6 kg up to 10 kg)
(0.77 mL size only)



For dogs over 22 lb up to 44 lb ONLY
(For dogs over 10 kg up to 20 kg)
(1.54 mL size only)



For dogs over 44 lb up to 88 lb ONLY
(For dogs over 20 kg up to 40 kg)
(3.08 mL size only)



For dogs over 88 lb up to 132 lb ONLY
(For dogs over 40 kg up to 60 kg)
(4.62 mL size only)

() Bracket text allows for alternative presentations of the same claim.

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BACK PANEL (CONT'D)

Step 1. Hold applicator (tube) in upright position away from your face and snap tip open by bending it and folding it back on itself.

Step 2. The dog should be standing for easy application. Part the hair and place applicator (tube) tip against the skin between shoulder blades.

Step 3. : Squeeze applicator firmly applying entire contents directly to skin. Do not allow product to run off. Do not have contact with treated area (application site) until it is completely dry.

It is recommended to reapply every 30 days or as needed, but DO NOT apply more than 1 applicator (tube) per month. When application is complete, follow the Container Handling instructions under the Storage and Disposal section below.

(ALTERNATE Step 3 Directions for larger dogs:

Step 3: Apply entire contents of tube evenly to (two)(or)(three)(or)(four) spots on the back from between the shoulder blades to the base of the tail. At each spot, part the hair until skin is visible. Place the tip of the applicator (tube) on the skin and gently squeeze a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot which could cause some of the solution to run off the side of the dog. Do not allow the product to run off. Do not have contact with the treated area (application site) until it is completely dry.

FIRST AID	
If in Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a physician if irritation persists.
If On Skin	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have a person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling the poison control center or doctor or going for treatment. You may also contact the Rocky Mountain Poison Center at 1-303-595-4869 for emergency medical treatment information.	

() Bracket text allows for alternative presentations of the same claim.

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BACK PANEL (CONT'D)

For 0.51 ml/0.77 ml/1.54 ml/3.08 ml/4.62 ml

(note to reviewer: appropriate dose size will be depending on package)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

WARNING. Causes substantial but temporary eye injury. Harmful if absorbed through skin or swallowed. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs and puppies only. Do not use on puppies under 8 weeks of age and weighing less than 4 lb/14 lb/22 lb/44 lb/88 lb (note to reviewer: weight used will be according to package size).

Do not use on dogs (male or female) intended for breeding, pregnant or nursing. Consult a veterinarian before using this product on debilitated, aged, or medicated dogs. Individual sensitivities, while rare, may occur after using any pesticide product. If signs continue, consult a veterinarian immediately. Certain medications can interact with pesticides.

PHYSICAL OR CHEMICAL HAZARDS

Flammable. Keep away from heat and open flame.

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in a cool, dry place inaccessible to children and pets.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: If empty, do not reuse the container. Place in trash or offer for recycling if available. If partly filled, call your local solid waste agency for disposal instructions. Never place unused products down any indoor or outdoor drain.

EPA Reg. No. 773-94
EPA Est. No. 6175-LA-1

Net Contents: X applicator(s), each 0.02 fl.oz. (0.51 mL) {Total X fl.oz (X mL)}
X applicator(s), each 0.03 fl.oz. (0.77 mL) {Total X fl.oz (X mL)}
X applicator(s), each 0.05 fl.oz. (1.54 mL) {Total X fl.oz (X mL)}
X applicator(s), each 0.10 fl.oz. (3.08 mL) {Total X fl.oz (X mL)}
X applicator(s), each 0.16 fl.oz. (4.62 mL) {Total X fl.oz (X mL)}

Made in the USA

Intervet Inc (d/b/a Merck Animal Health). LOGO Merck Animal Health
Summit, NJ 07068
Copyright xxxx All rights reserved. xxxxxxxx Rev. xx/xxxx

(Volume varies with size of animal for which package is intended and number of applicators per package. Product may be packaged in 1, 3, 4, 6, or 12 applicators per package. Total volume will correspond to number of applicators)

() Bracket text allows for alternative presentations of the same claim.

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APPLICATOR LABELING

ACTIVYL

For Dogs (and) (or) Puppies 8 weeks and older and

over (>) (greater than) 4 lb (pounds) (1.8 kg) and (up to) (less than or equal to) 14 lb (pounds) (6.6 kg) ONLY
over (>) (greater than) 14 lb (pounds) (6.6 g) and (up to) (less than or equal to) 22 lb (pounds) (10 kg) ONLY
over (>) (greater than) 22 lb (pounds) (10 kg) and (up to)(less than or equal to) 44 lb (pounds) (20 kg) ONLY
over (>)(greater than) 44 lb (pounds) (20 kg) and (up to)(less than or equal to) 88 lb (pounds) (40 kg) ONLY
over (>)(greater than) 88 lb (pounds) (40 kg) and (up to)(less than or equal to)132 lb (pounds) (60 kg) ONLY

Indoxacarb:19.53%

KEEP OUT OF REACH OF CHILDREN
WARNING
READ ENTIRE LABEL BEFORE USE

0.02 fl.oz. (0.51 mL) or
0.03 fl.oz. (0.77 mL) or
0.05 fl.oz. (1.54 mL) or
0.10 fl.oz. (3.08 mL) or
0.16 fl.oz. (4.62 mL) or

EPA Reg. No. 773-94
EPA Est. No. 6175-LA-1

Intervet Inc (d/b/a Merck Animal Health). LOGO Merck Animal Health

Intervet Inc.

Lot No:

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FOIL POUCH LABELING

DO NOT REMOVE APPLICATOR (TUBE) UNTIL READY TO USE

ACTIVYL for Dogs and Puppies

Alternate Brand Names:

ACTIVYL for Dogs or Puppies
ACTIVYL Spot-On for Dogs and Puppies
ACTIVYL Spot-On for Dogs or Puppies
ACTIVYL for Dogs
ACTIVYL Spot-On for Dogs

For Dogs (and) (or) Puppies 8 weeks and older and

over (>) (greater than) 4 lb (pounds) (1.8 kg) and (up to) (less than or equal to) 14 lb (pounds) (6.6 kg) ONLY
over (>) (greater than) 14 lb (pounds) (6.6 g) and (up to) (less than or equal to) 22 lb (pounds) (10 kg) ONLY
over (>) (greater than) 22 lb (pounds) (10 kg) and (up to)(less than or equal to) 44 lb (pounds) (20 kg) ONLY
over (>)(greater than) 44 lb (pounds) (20 kg) and (up to)(less than or equal to) 88 lb (pounds) (40 kg) ONLY
over (>)(greater than) 88 lb (pounds) (40 kg) and (up to)(less than or equal to)132 lb (pounds) (60 kg) ONLY

Indoxacarb: 19.53%

**KEEP OUT OF REACH OF CHILDREN
WARNING
READ ENTIRE LABEL BEFORE USE**

0.02 fl.oz. (0.51 mL) or
0.03 fl.oz. (0.77 mL) or
0.05 fl.oz. (1.54 mL) or
0.10 fl.oz. (3.08 mL) or
0.16 fl.oz. (4.62 mL) or

EPA Reg. No. 773-94
EPA Est. No. 6175-LA-1

Intervet Inc (d/b/a Merck Animal Health). LOGO Merck Animal Health

Lot No:

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FRONT PANEL AND/OR SIDE PANEL CLAIMS

1. Intended to be sold by veterinarians.
2. Intended to be dispensed (and)(or) sold through (by) licensed veterinarians and only to their clients for pets under a direct vet-client-patient relationship.
3. Product availability intended through licensed veterinarians.
4. Kills fleas that may cause disease, including bartonellosis and transmit tapeworms.
5. If there is a high risk of re-infestation or if the pet has fleas, once monthly application is recommended
6. Kills fleas that may cause (flea allergy dermatitis) (FAD).
7. If there is a high risk of re-infestation or if the pet has fleas which may cause (flea allergy dermatitis) (FAD), once monthly application is recommended.
8. (Alternate or brand name) kills fleas that may cause anemia.
9. (Alternate or brand name) kills fleas that may transmit tapeworms.
10. The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with (alternate or brand name) kills fleas
11. For the (prevention)(and)(treatment) of flea infestations on dogs (and/or) (puppies > 8 weeks) for (four)(4)(weeks) (one)(1)(month)
12. (Prevents) (and) (protects) against (re-)infestation (of fleas) for (four)(4)(weeks)
13. (Prevents) (and) (protects) against (re-)infestation (of fleas) for (one)(1)(month)
14. One treatment prevents flea infestations (on dogs) (and/or) (puppy > 8 weeks) for (four)(4)(weeks)
15. One treatment prevents flea infestations (on dogs) (and/or) (puppies > 8 weeks) for (one)(1)(month)
16. Protects (your dog) (and/or) (puppy > 8 weeks) from fleas for (four)(4)(weeks)
17. Protects (your dog) (and/or) (puppy > 8 weeks) from fleas for (one)(1)(month)
18. Monthly treatment (recommended) for optimal (control)(and)(prevention)(of fleas)(on your)(dog)(and/or)(puppy > 8 weeks)
19. Effective monthly (control) (prevention)(and)(treatment) of fleas (on dogs) (and/or) (puppies > 8 weeks)
20. Flea (control) (prevention)(and)(treatment) formulated for (dogs)(and)(puppies > 8 weeks)
21. (Controls)(Treatment against)(Protects against) (blood-feeding) (by) fleas
22. Monthly treatments are (recommended) for optimal (control) (and) (prevention) of flea(s) (infestations)
23. Prevents and controls re-infestations
24. For optimum treatment, control and prevention of adult year round treatment is recommended.
25. Prevents flea larval development
26. Larval flea stages in (the pet's) (your dog's) surroundings are killed following contact with (alternate or brand name) treated pet.

() Bracket text allows for alternative presentations of the same claim.

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FRONT PANEL AND/OR SIDE PANEL CLAIMS (cont'd)

27. Water-resistant
28. Waterproof
29. (Alternate or brand name) (This product) Remains effective even after (bathing) (water immersion), (or) (exposure to rain) (or) (sunlight)
30. (Alternate or brand name)(This product) Remains effective after (bathing) (and) (or) (swimming)
31. (Alternate or brand name)(This product) remains efficacious following (a) (shampoo treatment) (swimming) (and) (or) (exposure to rain) (or) (sunlight).
32. Starts killing fleas within 8 hours

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ALTERNATE MARKETING TEXT

1. Once-A-Month Topical Flea (Treatment) (Prevention) (Control) for (dogs) (and) (puppies > 8 weeks)
2. Once-A-Month Topical Flea (Treatment) (Prevention) (Control) for (dogs) (and) (puppies) > 8 weeks and older and weighing more than 4 lb.
3. (Once) monthly (a month) application (treatment) (for)(dogs) (and) (puppies > 8 weeks)
4. (Reapplication at monthly intervals) (Monthly reapplications) may be appropriate depending upon (the level of flea challenge) (and) (animal sensitivities) (i.e., flea allergy dermatitis).
5. X applicators
6. X monthly doses (applications)(treatments)
7. Quick drying (non-greasy)
8. Long Lasting (Fast Acting) for up to 1 month (30 days)
9. (Effective) Long-lasting protection for up to 1 month (30 days).
10. Easy to apply (spot-on) (topical) (application)(treatment)
11. Convenient (to use)(monthly use)(monthly treatment)
12. Easy (Convenient) to apply
13. Easy (spot on) (to use) application
14. (Convenient) (Single) (Spot) application
15. No (noticeable) odor.
16. Fragrance free
17. Formulated for dogs (and) (puppies) > 8 weeks and older and weighing more than 4 lb.
18. Monthly use breaks the flea life cycle
19. Questions (or) (comments) call (1-800-Tel. Number)(or)(Tel. No.)
20. For more information call (1-800- Tel. Number) (or Tel. No.)
21. For emergencies call (1-800- Tel. Number) (or) (Tel. No.)-same as above
22. If you have any questions, call Technical Services at (1-800- Tel. Number)(or) (Tel. No.)
23. (Manufacturer) (Satisfaction) Guaranteed or your money back.

() Bracket text allows for alternative presentations of the same claim.

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ALTERNATE MARKETING TEXT (cont'd)

24. Recommended year round (control) (treatment)(prevention) (against fleas)
25. Proven (control)(treatment)(prevention) for flea infestations
26. Protects (your) (dog) (and) (or) (puppy > 8 weeks) for (1 month)(one month)(a month)
27. (Alternate or brand name)(This product)(It) may also be used to (control) (prevent) infestation on flea-free (dogs) (and) (or) (puppies) > 8 weeks (of age) or older and weighing more than 4 lb., taken into a flea-contaminated environment.
28. Flea control for today's flea challenges
29. Indoxacarb is from the chemical class of oxadiazine insecticides
30. Excellent flea mortality
31. Pesticidal
32. (Indoxacarb is a)Voltage-dependent sodium channel blocker
33. Indoxacarb (the active) (in brand name) (in this product) blocks the channels that regulate the flow of sodium through the insect's nervous system.
34. (Convenient) (Single) (Spot) application that provides (control)(treatment)(protection) (of)(from)existing (flea)(infestations)
35. Protects against reinfestation(s) (of) (fleas) (on) (your) (dog) (puppy > 8 weeks)
36. When used monthly (alternate or brand name)-(this product) breaks the flea life cycle.
37. (Alternate or brand name) (This product) can be used on puppies > 8 weeks of age and weighing more than 4 lb.
38. Water-resistant
39. Waterproof
40. (Alternate or brand name)(This product) Remains effective even after (bathing) (water immersion), (or) (exposure to rain) (or) (sunlight)
41. (Alternate or brand name)(This product) Remains effective after (bathing) (and) (or) (swimming)
42. (Alternate or brand name)(This product) remains efficacious following (a) (shampoo treatment) (swimming) (and) (or) (exposure to rain) (or) (sunlight).

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NEXT DOSE STICKERS/ TREATMENT REMINDER (prototype)

Use these handy stickers to help remember when your pet's next dose is due. When you use the last tube in this package, consult your veterinarian and order more (product) (alternate or brand name), if needed.

Attach these (stickers) (reminders) to your (wall) (desk) calendar (daily planner) on the days the first dose is to be given, and on the same date for each of the remaining months.

Alternate text

It may be hard to remember when your (dog's) (and/or) (puppy's > 8 weeks) next dose is due. The following has been developed as a tool to help you keep track of every dose. When you use the last tube in this package, consult your veterinarian and order more (product) (alternate or brand name), if needed.

Attach these (stickers) (reminders) to your (wall) (desk) calendar (daily planner) on the days the first dose is to be given. Place another (sticker) (reminder) on the same date for the remaining months.

STICKER PROTOTYPE:

Picture of dog may vary. Up to 12 sticker count consistent with package



CARD Prototype:

PET'S NAME
PRODUCT: (preprinted alternate brand name)
DATE OF 1 st APPLICATION:
DATE OF 2 nd APPLICATION:
DATE OF 3 rd APPLICATION

() Bracket text allows for alternative presentations of the same claim.