

EEB

122804
SHAUGHNESSY NO.

REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 1-28-85 OUT 3-27-85

FILE OR REG. NO. 50658-EUP-R

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 12-21-84

DATE RECEIVED BY HED 1-25-84

RD REQUESTED COMPLETION DATE 4-16-85

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RD ACTION CODE/TYPE OF REVIEW 701/EUP

TYPE PRODUCT(S): I, D, H, F, N, R, S Insecticide

DATA ACCESSION NO(S). 255978

PRODUCT MANAGER NO. G. LaRocca (15)

PRODUCT NAME(S) Avermectin B₁

COMPANY NAME Merck Sharp & Dohme Research Laboratories

SUBMISSION PURPOSE Request by registrant for determination
of presence of endangered species in areas
of proposed treatment. Also label revisions.

SHAUGHNESSY NO.	CHEMICAL & FORMULATION	% A.I.
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122804	Avermectin B ₁	2%
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Pesticide Name: Avermectin B₁ (MK-936 0.15 EC)
(formerly AVID 0.15 EC)

100 Submission Purpose and Label Information

100.1 Submission Purpose and Pesticide Use

The purpose of this submission is to revise the Experimental Use Permit application previously reviewed (on March 20, 1984 - EEB file review #3) for use on citrus. In addition, rebuttal comments to EEB's previous citrus EUP review and additional test information were included with this submission. Finally, the registrant has requested a determination of the presence of endangered species in areas of the proposed treatments.

The revised EUP program is attached to this review. Salient revisions include name change, label changes, specifications on some treatment areas (e.g., counties and acres) and deletion of aerial sprays. This EUP review will consider ground applications (air blast) only. Minor changes in gallonage of water to use were also made.

The duration of this EUP is one year (Jan. 1 - Dec. 31, 1985). An evaluation of MK-936 0.15 EC on mites, white flies, various scale insects, citrus weevil, thrips, and mealybugs will be made. A study of effects on beneficial organisms including predators, parasites and pathogens of citrus insects and mites will be made. Worker exposure studies will also be made.

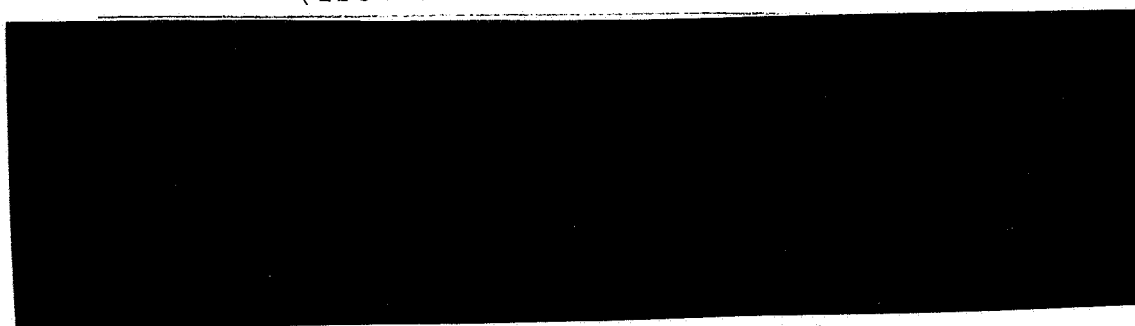
100.2 Formulation Information

MK-936 0.15 EC Miticide/Insecticide; formerly known as AVID 0.15 EC (7.5 lbs/gal).

Active Ingredient - Avermectin B₁:

Avermectin B₁ [A mixture of avermectins containing
≥ 80% avermectin B_{1a} (5-o-demethyl-avermectin Ala)
and ≤ 20% avermectin B_{1b} (5-o-dimethyl-25-de
(1-methylpropyl)-25 (1-methylpropyl)
avermectin Ala)]..... 2.0%

Inert Ingredients.....98.03
(from CSF dated December 20, 1934)



100.3 Application Methods, Directions. Rates

From EUP Label - (p. 3 of 4)
... "Evaluate applications in 100-1000 gallons of water per acre using standard ground equipment. All applications should be made with 0.20-0.25% oil in the spray mixture or with a minimum of 1.0 gallon of oil per acre."

Table 1

Rates to be evaluated in the EUP

<u>Crop</u>	<u>Pests</u>	<u>Concentrate Sprays^b</u> (per acre)	<u>Dilute Sprays^a</u> (per 100 Gal)
Citrus (round orange, grapefruit, lemon, lime and mandarine types)	Citrus rust mite	1/3-2/3	1.05 fl oz
	Citrus broad mite	pints	
	Citrus red mite	2/3-1 1/3	2.1 fl oz
	Citrus flat mite	pints	
	Texas citrus mite		
	Citrus bud mite		
	Yuma spider mite		
	Citrus thrips		
	Scale Insects		

a Do not apply more than 1000 gallons dilute spray per acre.

b For concentrate sprays - adjust the dosage to apply an amount not exceeding that used in a dilute spray.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Directions From Sec. G Program Outline

<u>State</u>	<u>Acres</u>	<u>Rates (lbs ai/A)</u>	<u>Applications (maximum)</u>
California	60	.00625-0.025	3
Arizona	30	.00625-0.025	3
Florida	60	.00625-0.025	3
Texas	30	.00625-0.025	3

The program plan calls for 40-80 acres to be treated once at 0.025 lb ai/A.

The applications will be made using standard air blast equipment in water volumes from 100-1000 gallons of finished spray. MK-936 0.15 EC will be tank mixed with 0.2-0.25% crop oil or a minimum of one (1) gallon per acre in all applications. Minimum plot sizes in efficacy trials will be 1-5 acres. In applicator exposure trials the area treated will range from 10-30 acres per site (4 sites).

Applications will be made postbloom (spring), summer and fall, if all three applications are used. For applicator exposure studies, applications are planned in late March in Florida and mid-April in California.

100.4 Target Organisms

Primary - citrus rust mite, citrus red mite, broad mite, yuma spider mite, citrus flat mite, Texas citrus mite.

Other pests - white fly, scale insects, weevil complex, thrips, mealybug.

100.5 Precautionary Labeling

Environmental Hazards

"This product is toxic to fish and wildlife. Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

"Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply when weather conditions favor drift from target areas. Do not apply within 200 feet of fish-bearing water."

"This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area."

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101 Hazard Assessment

101.1 Discussion

Citrus - Extent of use Pattern

The following data are taken from the 1978 USDA
Census of Agriculture.

Florida - all citrus

Harvested Acres - 910, 924
Harvested Trees - 67, 991, 357
Trees/Acre - 74.6

Bearing Trees - 62, 526, 535
Non-bearing Trees - 5, 464, 822
% nonbearing - 8%

Approx. Acres nonbearing - 73,255

California - all citrus

Harvested acres - 248,632
Harvested Trees - 27,000,000
Trees/Acre - 108.5

Bearing Trees - 25,600,000
Nonbearing Trees - 1,325,696
% nonbearing - 5%

Approx. Acres nonbearing - 12,218

Arizona - all citrus

Harvested Acres - 53,873
Harvested Trees - 4,680,000
Trees/Acre - 86.8

Bearing Trees - 4,530,000
Nonbearing Trees - 150,000
% nonbearing - 3%

Approx. Acres nonbearing - 1,728

Texas - all citrus

Harvested Acres - 87,654
Harvested Trees - 8,946,651
Trees/Acre - 102

Bearing Trees - 7,995,102
Nonbearing - 951,549
% nonbearing - 10.6%

Approx. Acres nonbearing - 9,329

Citrus - Aquatic Resources

Florida

Maximum citrus acreage is located in Florida. Over 70% of the U.S. orange and grapefruit acreage (700,000 A) are located there.

For this assessment citrus groves are divided into two scenarios: central county (a greater production of citrus per county); and coastal county. Central counties have numerous lakes, thought to have formed from ancient sink-holes. Florida Dept. of Environmental Regulations (DER) characterizes the groves there as having fine sandy soil on hilly terrain, with good drainage (some ground water drainage into lakes is expected). Groves may be planted to lake's edge; some have rim ditches or marsh buffers. Buffers of less than 30 yards are common.

The central Florida waters do not support a particularly good sport fishery since, particularly in the rivers, the water has a high tannic acid content (pH as low as 3.8). However, the aquatic invertebrate fauna is highly diverse. Fish include largemouth bass and chain pickerel, among others.

Florida DER expects little or no surface runoff from the hilly groves of the central area, but movement through the sand could contaminate lakes and connecting rivers. Soils and hydrosols are of low OM content, thus, organically bound chemicals may be moving through with little impediment. DER doubts any extensive use of tile and/or ditch drainage systems in the central state groves because they are expensive and unnecessary there.

The coastal groves are more subject to rainy and dry seasons, which determine whether groves may have to be pump-drained or irrigated. The rainy season coincides

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with most pesticidal applications, and pump drainage of groves could be expected. Most groves have ditch drainage. Ditches empty directly into canals and ultimately into the Intercoastal Waterway.

Ditches and canals of the coastal groves may be characterized by heavy "muck" (organic) soils and hydrosols, thus favoring retention of organically bound chemicals. They support amphibians, reptiles and fish including largemouth bass, bluegill, killifish and mosquito fish, among others. Aquatic invertebrates there are of course basic to these food chains.

Both of the citrus grove scenarios discussed represent significant opportunity for aquatic contamination through spray drift, direct application, surface runoff, and ground water drainage, or leaching.

Since the total of bearing and nonbearing Florida citrus acreage is very extensive and, in some localities, exclusive, any potential hazards to lakes, marshes, streams, and ditch canals may represent a significant risk of adverse effects.

California

This represents the second largest use of pesticides on citrus.

Aquatic communities are many and varied. Many man-made bodies of water such as irrigation ditches and canals, large and small reservoirs, and the California Aquaduct, are important aquatic resources. Natural and man-made ecosystems range in size from small vernal ponds to large impoundments, and from small streams to large rivers. The fish habitat in the San Joaquin Valley alone exceeds 6,000 miles of streams, canals, rivers, lakes, and reservoirs that support both cold and warmwater species.

Commercial citrus is concentrated in Southern California in Fresno, Kern, Orange, Riverside, San Bernadino, San Diego, Tulare and Ventura Counties.

Texas

(Soils, surface and ground water information taken from EAB files.)

The majority of the orange and grapefruit acreage in Texas occurs in a tri-county area bordering the Rio Grande River and Gulf of Mexico (Cameron, Hidalgo, Willacy Cos. - about 50,000 acres of citrus).

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The following characterizes the soils, water tables and pH;

<u>SCS Land Capability</u>	<u>Soil Series</u>	<u>Characteristics</u>
A	Delfina fine sandy loam	pH 6.6-7.8 seasonal high water table percolation rate of 2-6.3 in./hr. Texture 60% sand (of which 30% fine, 30% coarse) 30% silt, 10% clay.
B	Willacy fine sandy loam	Same as Delfina.
C	Camargo silty loam	pH 7.9-8.4 perched water table common after rain or irrigation. Percolation 0.6-2.0 in./hr. Texture 60% silt, 30% sand, 10% clay.

It is noted that some of these fields are tile-drained which can serve to discharge irrigation water applied to the orchards. The tile drain can be either deep tilled or shallow tilled and drain into discharge ditches. The composition of these ditches is generally soil and they flow into a common discharge basin.

Precipitation in the area ranges from 16-32 inches per year, with the pan evapotranspiration ranging from 80-112 inches per year, which results in a negative natural water balance. Supplemental irrigation rates are 2.5 acre feet per acre per annum.

Water Resources (Surface)

The Rio Grande is both the major watercourse within and the major water supply source for the Lower Rio Grande Valley. The flow of the Rio Grande is utilized by two major water impoundments along the Rio Grande. Falcon Reservoir, the first, located between Laredo and Brownsville, Texas, provides water for many uses. The second, Amistad Reservoir, located a short distance upstream from Del Rio, Texas, serves as the second source of water for the area.

Almost all the water used for consumptive purposes in the Lower Rio Grande Valley is supplied from the Rio Grande. Small reservoirs, such as Delta Lake, in east Hidalgo County, and Valley Acres Reservoir, north of Mercedes, are used for temporary storage.

Other surface waters of the Lower Rio Grande Valley include Laguna Madre, South Bay, Laguna Atascosa, Bahia Grande, Brownsville Ship Channel, Arroyo Colorado, North Floodway, and San Martin Lake. These hydrologic features are not used for water supply although they are utilized for nonconsumptive purposes.

(Ground Water)

The ground water resources of the Lower Rio Grand Valley area consists of three ground water reservoirs:

1. Linn-Faysville ground water reservoir
2. Lower Rio Grande
3. Mercedes-Sebastian

Water that is used for irrigation purposes is collected by ditch tile-drain systems, which carries the excess eastward to Rio Hondo and to a communal drainage basin near Harling (26°15' by 97°40'), with eventual discharge into the Gulf of Mexico. The drainage water is not used again for irrigation.

Surface runoff from Texas groves are not expected to be significant due to the hydrology of the area. Spray drift, however, may contaminate small ponds or streams near groves, so that caution needs to be exercised there. Drainage ditches and canals are not likely to have soils favoring the retention of organically bound chemicals.

101.2 Likelihood of Exposure to Nontarget Organisms

The proposed application rates are between 0.0625-0.025 lb. ai/A. The maximum use permitted under this EUP is 0.025 lb ai/A with three (3) possible applications throughout the growing season.

Theoretical terrestrial residues resulting from a single maximum application are:

Short grass	- 6	ppm
Long grass	- 2.7	ppm
Leafy crop, Leaves	- 3	ppm
Forage	- 1.5	ppm
Pod, seed containing	- 0.3	ppm
Fruit	- 0.15	ppm

In a direct application to water 6" deep, the following zero-hour residues would be expected:

<u>Rate</u>	<u>Concentration</u>
.00625	4.6 ppb
.025	18.3 ppb

The above rates reflect only maximum expected residues after a single application. With little or no hydrolysis, aquatic residues could increase to as much as 13.8 and 55 ppb respectively, after the maximum three (3) seasonal treatments.

Theoretical concentrations from maximum applications exceed LC₅₀ values for indicator freshwater fish species (96-hr LC₅₀ = 3 ppb) and freshwater invertebrates (48-hr LC₅₀ = 0.34 ppb). Thus, both RPAR and endangered species triggers are exceeded with direct applications to water.

Organisms whose indicator LC₅₀ or EC₅₀ are exceeded include: warmwater fish, coldwater fish, estuarine shrimp and freshwater invertebrates such as Daphnia magna. These levels also exceed the "no-observed-effect level" for warmwater fish (Bluegill NOEL = 2.3 ppb) in a 7-day flow-through bioassay) indicating that a similar hazard for stream organisms can be anticipated.

Based upon methods for application the treatments under this EUP may be expected to cause some acute mortality for fish and aquatic invertebrates if exposed to spray drift or runoff. Generally, the use on citrus trees is not expected to result in unreasonable toxicological hazard because the exposure is extremely limited by the EUP. Little or no hazard is expected for birds exposed to citrus residues.

Because of the proximity of citrus orchards to many estuaries (particularly in Florida) valid estuarine/marine testing as per 72-3 will be needed to assess hazard for a Sec. 3 registration. Chronic fish and aquatic invertebrates testing as per 72-4 will also be needed for this purpose (see 72-4 (a)(i)(ii) and (iv)(c) for "when required").

Avermectin - Honeybee hazard

Data submitted by the registrant indicate that avermectin is highly toxic to honeybees exposed to direct treatment or to dried residues on foliage.

Based on these data, the product label should bear the following statement:

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

With the submission of additional residual toxicity data, or more narrowly defined recommended rates of application, this precautionary labeling may be amended.

With regard to nontarget insect data, the information submitted is sufficient to fulfill the Agency's EUP requirements.

101.3 Endangered Species Considerations

Endangered fish and aquatic invertebrates exposed to aquatic residues from spray drift or runoff will be at risk from treatments of MK-936. Endangered Species risk triggers would be exceeded by aquatic residues ≥ 0.017 ppb (aquatic invertebrate) or ≥ 0.16 ppb (freshwater fish).

For purposes of this EUP authorized personnel in charge of treatments must ensure, through consultation with appropriate State Gov't. or regional U.S. Fish and Wildlife Service endangered species specialists, that they will not impact any endangered species through this experimental program. A label statement is recommended for this purpose (see sec. 101.5).

Certain endangered aquatic species have been identified by EEB as "listed" in the counties and/or general areas indicated by the registrant as the proposed treatment areas. It should be noted that EEB has not consulted the U.S. Fish and Wildlife Service in this matter. As a result the following listing may not reflect the full extent of endangered species present, or may reflect species whose status has changed.

EEB wishes to clearly state that we consider the burden of protecting endangered species to lie with the registrant and the field personnel actually conducting an experimental program. EEB provides the following listing with an explicit understanding that at this time adequate review and consultation required by the Endangered Species Act cannot be made without site specific information and further toxicity data. Burden of protecting endangered species therefore should lie with holder of the EUP and

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field personnel making applications of experimental materials. This may be most effectively accomplished by coordinating the field work with State and/or Federal Endangered Species experts (see recommended label statement).

The following species have been identified as potentially inhabiting the areas specified by the registrant:

Gila elegans - Maricopa, Pinal and Yuma Counties, Arizona

Ptychocheilus lucius - Maricopa, Pinal and Yuma Counties, Arizona

Poeciliopsis o. occidentalis - Maricopa, Pinal and Yuma Counties, Arizona

Plagopterus argentissimus - Maricopa, Pinal and Yuma Counties, Arizona

Salmo gilae - Maricopa County, Arizona

Gasterosteus aculeatus williamsoni - Ventura County, California

Salmo aquabonita whitei - Tulare County, California

Acipenser brevirostrum - Lake County, Florida

Pomacea paludosa* - Highlands, Lake, and Orange Counties, Florida

* N.B. - Pomacea paludosa, the Apple snail, while not an endangered species itself, is the virtual sole food source of the endangered bird Rostrhamus sociabilis plumbeus (Florida Everglades Kite). A threat to the Apple snail therefore represents a direct threat to the endangered kite.

101.4 Adequacy of Toxicity Data

This section addresses material submitted previously under Accession No. 252115 and new material submitted under Accession No. 255978 with this review request.

Response to rebuttal comments in Accession No. 255978 Sec. C2a.

Rebuttal Comment -

Vapor pressure/aeration studies - the registrant claims that "because there is no detectable vapor pressure for

MK-936 even up to 125°C, aeration in the above studies (shrimp and blue crab acute toxicity) would not have caused loss of the material."

EEB response - EEB acknowledges that lack of appreciable vapor pressure may reduce the likelihood of loss of nominal concentration through aeration of a test compound and that MK-936 appears to have negligible (not zero) vapor pressure. In view of this argument EEB will consider accepting the nominal concentrations in the shrimp and blue crab studies submitted under Accession No. 252115 if the registrant demonstrates through a laboratory aeration study, that no such loss occurs in practice (see Section 101.5).

Note that the blue crab study can never be considered as fully satisfying a guidelines requirement since this is not an acceptable test species [see Pesticide Assessment Guidelines, Subdivision E, 72-3(b)(2), which calls for this requirement to be fulfilled as fish, shrimp and mollusc]. However, the crab data are useful to some extent and can be used in our hazard assessment if the aeration test cited above is performed.

The raw data on replicates submitted with Accession No. 255978 tabs C2b1, C2b2 and C2b3 which supplement the previously submitted oyster, shrimp and blue crab acute toxicity studies (Accession No. 252115), are acceptable and support the analyses. However, for reasons stated above, only the oyster study may be upgraded to fulfilling a guidelines requirement at this time.

101.5 Additional Data Required

No additional data are required to support the EUP application.

Sec. 3 registration requirements outstanding at this time include:

1. An acute toxicity study of a shrimp as per 72-3 or repair the previously submitted shrimp study which was aerated without measuring analytical concentrations of toxicant. In consideration of the data on negligible vapor pressure of MK-936 EEB will allow repair by performing an aeration study without organisms, which measures potential loss of MK-936 by aeration in 3-5 replicate vessels containing nominal toxicant solutions of 1-2 ppb technical MK-936 in 28% saline solution at 22°C. Rate of aeration should be the

same as conducted during the pink shrimp study done by EG & G Bionomics. The registrant must provide a comparison of the original (EG & G) aeration and the repair test aeration. The object of this test is to measure analytical concentrations (and loss from nominal) in tests simulating the EG & G Bionomics study of pink shrimp (Penaeus duorarum; Accession No. 252115).

2. Submit an acute toxicity of a marine/estuarine fish species as per 72-3 of the Pesticide Assessment Guidelines, Subdivision E.
3. Submit chronic fish and aquatic invertebrate tests as per 72-4 of the Pesticide Assessment Guidelines, Subdivision E.
4. Additional ecological effects data may be required pending the review of the above studies and the environmental fate data.

101.6 Adequacy of Labeling

The proposed EUP "Environmental Hazard" labeling section is inadequate.

The following statement must be added to insure protection of endangered species:

In order to insure protection of endangered species from exposure to this experimental pesticide, persons authorized to conduct experiments with this product must first consult with State or Federal endangered species authorities responsible for the treatment area.

We note that one of the label statements incorporates a 200 foot "lay-off" distance to fish-bearing waters. EEB does not recommend specific buffer zones and does not understand how they arrived at "200 feet" for this label. While we do not object to this measure for the EUP, we want to make it clear that this 200-ft. zone statement may not be invoked to imply safety for fish or other aquatic organisms nor may it otherwise mitigate the need for advanced "tier" testing or formal consultation with USDI's Office of Endangered Species regarding this or any Section 3

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application for registration.

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Conclusions

EEB has reviewed the revised EUP application for use of Avermectin B₁ (MK-936 0.15 EC) on citrus. The EUP provides for very limited exposure, yet certain ecologically sensitive areas may be exposed (Sec. 101.1). Endangered species may also be exposed (101.3).

We find that the material is very highly acutely toxic and could be expected to cause some acute hazards in aquatic resources receiving runoff or drift from citrus orchards. However, overall we expect this EUP to provide for minimal risks for nontarget organisms (Sec. 101.2).

We recommend additional label precautionary statements to protect endangered species and specify precautions and limitations associated with a proposed "lay-off" distance (Sec 101.6). We indicate endangered species and locations, when possible, and explain why ultimate compliance responsibility for endangered species protection, lies with the registrant and the users of this experimental material (Sec. 101.3).

We accept the "raw" replicate data submitted as supporting the statistical analyses for some previously submitted tests (Sec. 101.4). We indicate outstanding data requirements and outline an experiment to repair two previously submitted studies (Sec. 101.5).

John Bascietto 4/4/85

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SECTION G

Proposed Experimental Program

Avermectin science review

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Pages 17 through 36 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients
 - ☐ Identity of product impurities
 - ☐ Description of the product manufacturing process
 - ☐ Description of product quality control procedures
 - ☐ Identity of the source of product ingredients
 - ☐ Sales or other commercial/financial information
 - ☐ A draft product label
 - ☐ The product confidential statement of formula
 - ☐ Information about a pending registration action
 - ☒ FIFRA registration data
 - ☐ The document is a duplicate of page(s) _____
 - ☐ The document is not responsive to the request
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
