Appendix B is added to Part 946 to read as follows:

Appendix B to Part 946—Airport Tables

''A'' Level Service Airports

*Akron, OH ....CAK
*Albany, NY ....ALB
*Atlanta, GA ....ATL
*Baltimore, MD....BWI
*Boston, MA ....BOS
Charlotte, NC....CLT
*Chicago-O'Hare (AV), IL ....ORD
Cincinnati, OH ....CVG
Columbus, OH ....CMH
*Dayton, OH....DAY
*Des Moines, IA....DSM
*Detroit, MI ....DTW
*Fairbanks, AK ....FAI
*Fresno, CA ....FAT
*Greensboro, NC ....GSO
*Hartford, CT ....BDL
*Indianapolis, IN....IND
*Kansas City, MO....MCI
*Lansing, MI....LAN
Las Vegas, NV ....LAS
Los Angeles (AV), CA....LAX
*Louisville, KY ....SDF
*Milwaukee, WI....MKE
*Minneapolis, MN ....MSP
*Newark, NJ....EWR
*Oklahoma City, OK ....OKC
Phoenix, AZ....PHX
*Portland, OR ....PDX
*Providence, RI ....PVD
*Raleigh, NC....RDU
*Richmond, NC....RIC
*Rochester, NY....ROC
*Rockford, IL ....RFD
*San Antonio, TX....SAT
San Diego, CA....SAN
*San Francisco, CA ....SFO
*Spokane, WA ....GEG
*Syracuse, NY....SYR
Tallahassee, FL ....TLH
Tulsa, OK ....TUL

''B'' Level Service Airports

*Baton Rouge, LA ....BTR
*Billings, MT....BIL
*Charleston, WV....CRW
*Chattanooga, TN ....CHA
Colorado Springs, CO....COS
Daytona Beach, FL ....DAB
El Paso, TX ....ELP
Flint, MI....FNT
Fort Wayne, IN ....FWA
Honolulu, HI ....HNL
*Huntsville, AL....HSV
*Knoxville, TN ....TYS
*Lincoln, NE....LNK
Lubbock, TX....LBB
*Madison, WI ....MSN
*Moline, IL ....MLI
*Montgomery, AL....MGM
*Muskegon, MI....MKG
*Norfolk, VA....ORF
Peoria, IL ....PIA
*Savannah, GA....SAV
*South Bend, IN ....SBN
Tucson, AZ ....TUS
*West Palm Beach, FL ....PBI
*Youngstown, OH....YNG

''C'' Level Service Airports

Abilene, TX....ABI
Allentown, PA ....ABE
Asheville, NC ....AVL
Athens, GA ....AHN
Atlantic City, NJ....ACY
Augusta, GA ....AGS
Austin, TX....AUS
Bakersfield, CA ....BFL
Bridgeport, CT ....BDR
Bristol, TN....TRI
Casper, WY....CPR
Columbia, MO....COU
Columbus, GA....CSG
Dubuque, IA ....DBQ
Erie, PA....ERI
Eugene, OR ....EUG
Evansville, IN ....EVV
Fargo, ND ....FAR
Fort Smith, AR ....FSM
Grand Island, NE....GRI
Helena, MT....HLN
Huntington, WV ....HTS
Kahului, HI....OGG
Key West, FL....EYW
Lewiston, ID....LWS
Lexington, KY ....LEX
Lynchburg, VA ....LYH
Macon, GA....MCN
Mansfield, OH....MFD
Meridian, MS ....MEI
Olympia, WA....OLM
Port Arthur, TX ....BPT
Portland, ME....PWM
Rapid City, SD ....RAP
Redding, CA ....RDD
Reno, NV ....RNO
Roanoke, VA ....ROA
Rochester, MN....RST
Salem, OR ....SLE
Santa Maria, CA ....SMX
Sioux City, IA ....SUX
Springfield, IL ....SPI
Stockton, CA ....SCK
Toledo, OH ....TOL
Waco, TX ....ACT
Waterloo, IA ....ALO
Wilkes-Barre, PA ....AVP
Williamsport, PA ....IPT
Wilmington, DE ....ILG
Worcester, MA ....ORH
Yakima, WA ....YKM

*Long-line RVR designated site.

[FR Doc. 96–19412 Filed 7–30–96; 8:45 am]

BILLING CODE 3510–12–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Tables and Chewable Cubes

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental new animal drug applications (NADA's) filed by Merck Research Laboratories, Division of Merck & Co., Inc. The supplemental NADA's provide for label changes including a revised indication and limitation for oral use of ivermectin tablets and chewable cubes for dogs to prevent canine heartworm disease.

EFFECTIVE DATE: July 31, 1996.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0137.

SUPPLEMENTARY INFORMATION: Merck Research Laboratories, Division of Merck & Co., Inc., P.O. Box 2000, Rahway, NJ 07065, filed supplemental NADA's 138–412 and 140–886, which provide for use of Heartgard® (ivermectin) Tablets and Heartgard® (ivermectin) Chewables for dogs. The supplemental NADA's amend the approved indications for use to read ''To prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection.'' The supplements also amend the limitations pertaining to puppies to state ''Recommended for dogs 6 weeks of age and older.'' These changes are necessary to be consistent with the labeling for Heartgard-30® Plus (ivermectin and pyrantel pamoate) NADA 140–971, as published in the Federal Register of April 15, 1996 (61 FR 15185 at 15186). The supplemental NADA's 138–412 and 140–886 are approved as of June 14, 1996, and the regulations are amended in 21 CFR 520.1193(c)(2) and (c)(3) to reflect the approval.

Approval of these supplements did not require submission of new data and information. Therefore, freedom of information summaries under part 20 (21 CFR part 20) and 21 CFR 514.11(e)(2)(ii) are not required.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), these approvals do not qualify for marketing exclusivity because the supplements do not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approvals and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.24(d)(1)(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.1193 is amended by revising paragraphs (c)(2) and (c)(3) to read as follows:

§ 520.1193 Ivermectin tablets and chewable cubes.

* * * * *

(c) * * *

(2) *Indications for use.* To prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection.

(3) *Limitations.* Use once-a-month. Recommended for dogs 6 weeks of age and older. Initial use within 1 month after first exposure to mosquitoes. Final use within 1 month after last exposure to mosquitoes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: June 9, 1996.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 96–19410 Filed 7–30–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 803

RIN 0910–AA09

Docket No. [91N–0295]

Medical Devices; Medical Device Reporting; Baseline Reports; Stay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: In response to numerous requests for the Food and Drug Administration (FDA) to further consider comments concerning manufacturer medical device reporting (MDR) baseline reporting requirements, FDA is staying the effective date of certain portions of the baseline reporting requirements. The stay of these requirements will allow FDA to further evaluate the issues raised by the comments and to determine whether the requirements should be revised.

EFFECTIVE DATE: July 31, 1996.

FOR FURTHER INFORMATION CONTACT: Earl W. Robinson, Center for Devices and Radiological Health (HFZ–530), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–2735.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 11, 1995 (60 FR 63578) FDA published a final rule amending part 803 (21 CFR part 803) requiring medical device manufacturers to submit certain reports relating to adverse events (hereinafter referred to as the December 1995 final rule). The effective date of this rule was initially to be April 11, 1996. However, on April 11, 1996 (61 FR 16043), FDA extended the effective date to July 31, 1996.

Under the December 1995 final rule, manufacturers were required to submit individual reports of adverse events on a monthly basis, as well as annual baseline reports. Section 803.55 requires that the baseline reports include information specifically identifying a device for which an adverse event has been submitted, the number of devices manufactured and distributed in the last 12 months, an estimate of the number of devices in current use, and a brief description of any methods used to estimate the number of devices distributed and in current use. Among the primary purposes of these baseline data requirements is to provide information on population exposure to a particular device which together with the number of adverse event reports would provide relevant information about the rate of reported events for a particular device to aid the agency in evaluating an adverse event's significance. For example, information concerning the number of devices manufactured, distributed or in current use (hereinafter referred to as denominator data) is intended to enable the agency to determine how many people are exposed to potential risk from a device and whether 100 malfunction reports for a particular device represents a .001 percent (100 of 10,000,000) reported failure or a 10 (100 of 1,000) percent reported failure.

After issuing the December 11, 1995, final rule, FDA received numerous requests for reconsideration of the baseline reporting requirements. Specifically, industry objected that the requirements for denominator data were burdensome. These comments led FDA to meet with the Health Industry Manufacturers Association (HIMA) and several other industry representatives on April 19, May 23, June 13, and July 1, 1996. During these meetings and FDA internal meetings, issues concerning industry burdens and FDA evaluation of data were put forth that had previously not been considered.

Specifically, issues were raised about the ability to derive accurate information about adverse event rates of devices by the denominator data. The agency needs additional time to consider and better understand methods used to derive denominator estimates. FDA believes that a pilot program to analyze how certain variables affect the denominator data and how that data is used would allow the agency to implement denominator data requirements to evaluate the rate of and relative impact of adverse events more accurately. FDA intends to evaluate these issues further, and with the cooperation of industry in the near future, to implement such a pilot program, and subsequently to analyze these factors. Assuming that there is sufficient participation in the program, FDA anticipates that the completion of a successful pilot program would take from 12 to 18 months.

Because of the need for further analysis of variables affecting denominator data, FDA believes that baseline denominator data requirements should be stayed. The agency believes a pilot program may allow FDA to analyze the best possible means to obtain denominator data. At the completion of the pilot program, or a determination that because of inadequate participation, the pilot program is not feasible, FDA will either lift the stay of the December 1995 final rule baseline denominator reporting requirements, retain the stay, or proceed to revise these requirements.

The Administrative Procedure Act (Pub. L. 79–404) and FDA regulations provide that the agency may issue a regulation without notice and comment procedures when the agency for good cause finds (and incorporates the finding and a brief statement of reasons thereof in the rules issued) that notice and public comment procedures thereon are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(8); § 10.40(e)(1)).) FDA finds that there is good cause for dispensing with notice and comment procedures to stay the effective date of the manufacturer baseline reporting requirements for denominator data (§ 803.55((b)(9) and (10)) (corresponding with data elements 15 and 16 on FDA Form 3417) because such notice and comment procedures are impracticable and contrary to the public interest.