

rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule. Likewise, significant adverse comments submitted to the direct final rule will be considered as comments to the companion proposed rule and the agency will consider such comments in developing a final rule. FDA will not provide additional opportunity for comment on the companion proposed rule.

If a significant adverse comment applies to an amendment, paragraph, or section of this direct final rule and that provision may be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not the subject of a significant adverse comment. A full description of FDA's policy on the direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466).

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) and (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.

IV. Federalism

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. Analysis of Impacts

FDA has examined the impacts of the direct final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits

(including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this direct final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this direct final rule simply incorporates three existing FOIA exemptions, the agency certifies that it will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million, adjusted annually for inflation. As noted previously, we find that this final rule would not have an effect of this magnitude on the economy.

VI. Paperwork Reduction Act of 1995

The direct final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any written comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner

of Food and Drugs, 21 CFR part 20 is amended as follows:

PART 20—PUBLIC INFORMATION

■ 1. The authority citation for part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

■ 2. Section 20.65 is added to read as follows:

§ 20.65 National defense and foreign policy.

(a) Records or information may be withheld from public disclosure if they are:

(1) Specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy; and

(2) In fact properly classified under such Executive order.

(b) [Reserved]

■ 3. Section 20.66 is added to read as follows:

§ 20.66 Internal personnel rules and practices.

Records or information may be withheld from public disclosure if they are related solely to the internal personnel rules and practices of the Food and Drug Administration (FDA). Under this exemption, FDA may withhold records or information about routine internal agency practices and procedures. Under this exemption, the agency may also withhold internal records whose release would help some persons circumvent the law.

■ 4. Section 20.67 is added to read as follows:

§ 20.67 Records exempted by other statutes.

Records or information may be withheld from public disclosure if a statute specifically allows the Food and Drug Administration (FDA) to withhold them. FDA may use another statute to justify withholding records and information only if it absolutely prohibits disclosure, sets forth criteria to guide our decision on releasing material, or identifies particular types of matters to be withheld.

Dated: August 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–19996 Filed 9–1–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation and Injectable Dosage Form New Animal Drugs; Ivermectin Injection

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 a supplemental new animal drug application (NADA) filed by Merial Ltd. The supplemental NADA provides for an increased period of protection from reinfection with three species of internal parasites of cattle following administration of ivermectin solution by subcutaneous injection.

DATES: This rule is effective September 2, 2004.

FOR FURTHER INFORMATION CONTACT: Janis Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578, e-mail: janis.messenheimer@fda.gov.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640, filed a supplement to NADA 128-409 for IVOMEK (ivermectin) Injection for Cattle and Swine. The supplemental application provides for an increased period of protection from reinfection with three species of internal parasites of cattle following administration of ivermectin solution by subcutaneous injection. Specifically, the period of persistent effectiveness is increased from 14 days to 28 days for *Oesophagostomum radiatum*, and from 14 days to 21 days for *Trichostrongylus axei* and *Cooperia punctata*. A veal calf warning statement is being added because residue depletion data for this class of cattle has not been submitted to the application. The supplemental NADA is approved as of August 16, 2004, and 21 CFR 522.1192 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning August 16, 2004. Exclusivity applies only to the extension of the persistent effectiveness claims for *O. radiatum* from 14 days after treatment to 28 days after treatment, and for *T. axei* and *C. punctata* from 14 days after treatment to 21 days after treatment, for which new data were required.

The agency has determined under 21 CFR 25.33(a)(1) 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION AND INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 522.1192 is amended in paragraphs (a)(1), (a)(2), and (a)(3) by removing "sterile aqueous"; and by revising paragraphs (b) and (d)(2)(i) through (d)(2)(iii) to read as follows:

§ 522.1192 Ivermectin injection.

* * * * *

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 050604 for use as in paragraph (d) of this section.

(2) No. 059130 for use as in paragraphs (d)(2), (d)(3), (d)(4), and (d)(6) of this section of this section.

* * * * *

(d) * * *

(2) * * *

(i) *Amount.* 200 micrograms per kilogram of body weight by subcutaneous injection.

(ii) *Indications for use*—For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei*, *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum*); lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); grubs (parasitic stages) (*Hypoderma bovis*, *H. lineatum*); sucking lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mites (scabies) (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*). For No. 059130 in § 510.600(c) of this chapter: It is also used to control infections of *D. viviparus* for 28 days after treatment; *O. ostertagi* for 21 days after treatment; and *H. placei*, *T. axei*, *C. punctata*, *C. oncophora*, and *O. radiatum* for 14 days after treatment. For No. 050604 in § 510.600(c) of this chapter: To control infections and to protect from reinfection with *D. viviparus* and *O. radiatum* for 28 days after treatment; *O. ostertagi*, *T. axei*, and *C. punctata* for 21 days after treatment; *H. placei* and *C. oncophora* for 14 days after treatment.

(iii) *Limitations.* Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Not for intravenous or intramuscular use. Do not use in other animal species because severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

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Dated: August 25, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 04-19984 Filed 9-1-04; 8:45 am]

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