(3) No. 000856 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(D), (d)(1)(ii), (d)(1)(iii), (d)(3)(i)(A), (d)(3)(ii), and (d)(3)(iii).

* * * * *

(d) * * *

(3) *Pasture cattle (slaughter, stocker, and feeder steers and heifers)*—* * *

* * * * *

Dated: December 23, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04–131 Filed 1–5–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin

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 topical use of ivermectin on cattle to control infections and prevent reinfection with certain species of external and internal parasites.

DATES: This rule is effective January 6, 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: *jmessenh@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640, filed a supplement to NADA 140–841 for IVOMEC (ivermectin) Pour-On for Cattle. The application provides for topical use of 0.5 percent ivermectin solution on cattle to control infections and prevent reinfection with *Oesophagostomum radiatum* and *Dictyocaulus viviparus* for 28 days after treatment, *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment, *C. surnabada* for 14 days after treatment, and *Damalinia bovis* for 56 days after treatment. The NADA is approved as of November 24, 2003, and § 524.1193 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, the regulation is revised to remove two species of parasites, *Oesophagostomum venulosum* and *Chorioptes bovis*, which were codified in error during the original approval NADA 140–841 (55 FR 50551, December 7, 1990). Also at this time, the indication for *Cooperia* spp. is speciated as *Cooperia oncophora*, *C. punctata*, and *C. surnabada* to conform with current labeling practices. A veal calf warning statement is being added because residue depletion data for this class of cattle has not been submitted to the application.

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 November 24, 2003. 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 *C. punctata* and *T. axei* from 14 days after treatment to 21 days after treatment, and to the new persistent effectiveness claims for *D. viviparus*, *C. surnabada*, and *D. bovis* for which new data were required.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

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 524

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

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

■ 2. Section 524.1193 is amended by revising paragraphs (b), (e)(1), and (e)(2), and by adding two sentences to paragraph (e)(3) to read as follows:

§ 524.1193 Ivermectin topical solution.

* * * * *

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

(1) No. 050604 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(iii), and (e)(3) of this section.

(2) Nos. 051259, 051311, 058829, 059130, and 066916 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(ii), and (e)(3) of this section.

* * * * *

(e) *Conditions of use in cattle*—(1) *Amount.* One mL per 22 pounds (0.5 milligram per kilogram) of body weight applied topically to the back of the animal.

(2) *Indications for use*—(i) It is used for the treatment and control of: Gastrointestinal roundworms (adults and fourth-stage larvae) *Ostertagia ostertagi* (including inhibited stage), *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. surnabada*, *Oesophagostomum radiatum*; (adults) *Strongyloides papillosus*, *Trichuris* spp.; lungworms (adults and fourth-stage larvae) *Dictyocaulus viviparus*; cattle grubs (parasitic stages) *Hypoderma bovis*, *H. lineatum*; mites *Sarcoptes scabei* var. *bovis*; lice *Linognathus vituli*, *Haematopinus eurysternus*, *Damalinia bovis*, *Solenoptes capillatus*; and horn flies *Haematobia irritans*.

(ii) It controls infections and prevents reinfection with *O. ostertagi*, *O. radiatum*, *H. placei*, *T. axei*, *C. punctata*, and *C. oncophora* for 14 days after treatment.

(iii) It controls infections and prevents reinfection with *O. radiatum* and *D. viviparus* for 28 days after treatment, *C. punctata* and *T. axei* for 21 days after treatment, *H. placei*, *C. oncophora*, and *C. surnabada* for 14 days after treatment, and *D. bovis* for 56 days after treatment.

(3) * * * A withdrawal period has not been established for this product on preruminating calves. Do not use on calves to be processed for veal.

Dated: December 24, 2003.

Steven D. Vaughn,

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

[FR Doc. 04–130 Filed 1–5–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9110]

RIN 1545–BA85

Section 42 Carryover and Stacking Rule Amendments

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that amend several existing regulations concerning the low-income housing tax credit. The regulations primarily reflect changes to the law made by the Community Renewal Tax Relief Act of 2000 and affect owners of low-income housing projects who claim the credit and the State or local housing credit agencies who administer the credit.

DATES: *Effective Date:* These regulations are effective January 6, 2004.

Applicability Dates: For dates of applicability of these regulations, see §§ 1.42–12(a)(2) and (3), and 1.42–14(l)(2).

FOR FURTHER INFORMATION CONTACT: Lauren R. Taylor (202) 622–3040 or Christopher J. Wilson (808) 539–2874 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

On July 7, 2003, the IRS published a notice of proposed rulemaking in the **Federal Register** (68 FR 40218) proposing amendments to the Income Tax Regulations (26 CFR part 1) under section 42 of the Internal Revenue Code. These amendments provide guidance regarding changes to section 42 made by the Community Renewal Tax Relief Act of 2000 (Public Law 106–554) (2000 Act) and make certain changes to the regulations to help facilitate the electronic filing (E-filing) of income tax returns.

One commentator submitted written comments in response to the notice of proposed rulemaking. A public hearing was scheduled for September 23, 2003, pursuant to a notice of public hearing published simultaneously with the notice of proposed rulemaking. The IRS received one request to speak at the public hearing. This request was withdrawn before the hearing date. On September 15, 2003, the IRS published a notice (68 FR 53926) canceling the public hearing on the proposed regulations. After consideration of the comments received, the proposed regulations are adopted as revised by this Treasury decision. The revisions are discussed below.

Explanation of Provisions

Section 42 provides for a low-income housing tax credit that may be claimed as part of the general business credit under section 38. In general, the credit is allowable only if the owner of a qualified low-income building receives a housing credit allocation from a State or local housing credit agency (Agency) of the jurisdiction where the building is located.

In general, an allocation must be made not later than the close of the calendar year in which the building is placed in service. Under section 42(h)(1)(E), an allocation (carryover allocation) may be made to a ''qualified building'' that has not yet been placed in service, provided the building is placed in service not later than the close of the second calendar year following the calendar year of the allocation. Section 42(h)(1)(F) provides rules for multi-building projects receiving project-based carryover allocations. Following the changes made by the 2000 Act, section 42(h)(1)(E)(ii) defines a qualified building as any building that is part of a project if the taxpayer's basis in the project (as of the later of the date which is 6 months after the date that the allocation was made or the close of the calendar year in which the allocation is made) is more than 10 percent of the taxpayer's reasonably expected basis in the project (as of the close of the second calendar year following the calendar year of the allocation).

The commentator recommended revising § 1.42–6(a)(2) of the proposed regulations to clarify that each building in a multi-building project receiving a project-based carryover allocation under section 42(h)(1)(F) need not separately meet the 10 percent basis requirement. The commentator states that the proposed regulations appear to require that each building in a multi-building project that receives a project-based carryover allocation must meet the 10 percent basis requirement separately. The proposed regulations do not require that each building in a multi-building project satisfy the 10 percent basis requirement separately for project-based carryover allocations made under section 42(h)(1)(F). For allocations made under section 42(h)(1)(F), the 10 percent basis requirement is only required to be met on a project basis. The final regulations clarify this issue.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulations do not impose a new collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking that preceded this Treasury decision was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal authors of these regulations are Christopher J. Wilson and Lauren R. Taylor, Office of the Associate Chief Counsel (Passthroughs and Special Industries), IRS. However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

■ Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *

■ Par. 2. Section 1.42–6 is amended by:

■ 1. Revising paragraphs (a), (b)(4) *Example 2,* (c)(1), (c)(3), (d)(2)(viii), and (d)(4)(i).

■ 2. Removing the word ''September'' from paragraph (b)(4) *Example 1.* and adding the word ''May'' in its place; removing the year ''1993'' each place it appears and by adding the year ''2003'' in its place; and removing the year ''1995'' and adding the year ''2005'' in its place.

■ 3. Removing the language ''by the close of the calendar year of the allocation'' from the first and last sentences of