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 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: 21 U.S.C. 360b.

§ 520.2456 [Amended]

■ 2. Section 520.2456 is amended in paragraph (b) by removing ''*Sponsor*. See 000010'' and by adding in its place ''*Sponsors*. See Nos. 000010 and 059130'', and in paragraph (d)(2) by removing ''*Treponema*'' and by adding in its place ''*Brachyspira*''.

Dated: July 11, 2005.

Linda Tollefson,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 05–14696 Filed 7–25–05; 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; Doramectin

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 Pfizer, Inc. The supplemental NADA provides for a period of protection from reinfestation with two species of external parasites following topical administration of doramectin solution on cattle.

DATES: This rule is effective July 26, 2006.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.gov*.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141–095 for DECTOMAX (doramectin) Pour-On Solution for Cattle. The supplemental application provides for a period of protection from reinfestation with two species of external parasites following topical administration of doramectin solution on cattle. Specifically, the period of persistent effectiveness is 42 days for *Linognathus vituli* and 77 days for *Bovicola (Damalinia) bovis*. The supplemental NADA is approved as of June 23, 2005, and 21 CFR 524.770 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 June 23, 2005. Exclusivity applies only to the persistent effectiveness claims for the two species of external parasites listed previously in this document.

FDA 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 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 524.770 is amended by revising paragraph (e)(2) to read as follows:

§ 524.770 Doramectin.

* * * * *

(e) * * *

(2) *Indications for use*. For treatment and control of gastrointestinal roundworms: *Ostertagia ostertagi* (adults and fourth-stage larvae), *Ostertagia ostertagi* (inhibited fourth-stage larvae), *Ostertagia lyrata* (adults), *Haemonchus placei* (adults and fourth-stage larvae), *Trichostrongylus axei* (adults and fourth-stage larvae), *Trichostrongylus colubriformis* (adults and fourth-stage larvae), *Cooperia oncophora* (adults and fourth-stage larvae), *Cooperia punctata* (adults and fourth-stage larvae), *Cooperia pectinata* (adults), *Cooperia surnabada* (adults), *Bunostomum phlebotomum* (adults), *Oesophagostomum radiatum* (adults and fourth-stage larvae), *Trichuris spp.* (adults); lungworms: *Dictyocaulus viviparus* (adults and fourth-stage larvae); eyeworms: *Thelazia gulosa* (adults), *Thelazia skrjabini* (adults); grubs: *Hypoderma bovis* and *Hypoderma lineatum*; sucking lice: *Linognathus vituli*, *Haematopinus eurysternus*, and *Solenopotes capillatus*; biting lice: *Bovicola (Damalinia) bovis*; mange mites: *Chorioptes bovis* and *Sarcoptes scabiei*; horn flies: *Haematobia irritans*; and to control infections and to protect from reinfection with *Cooperia oncophora*, *Dictyocaulus viviparus*, *Ostertagia ostertagi*, and *Oesophagostomum radiatum* for 28 days; and with *Cooperia punctata* and *Haemonchus placei* for 35 days after treatment; and to control infestations and to protect from reinfestation with *Linognathus vituli* for 42 days and with *Bovicola (Damalinia) bovis* for 77 days after treatment.

* * * * *

Dated: July 11, 2005.

Steven D. Vaughn,

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

[FR Doc. 05–14630 Filed 7–25–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 549

[BOP–1111–F]

RIN 1120–AB11

Inmate Fees for Health Care Services

AGENCY: Bureau of Prisons, Justice.

ACTION: Final rule.

SUMMARY: The Bureau of Prisons (Bureau) finalizes rules describing procedures we will follow for charging inmates fees for certain kinds of health services, as required under the Federal Prisoner Health Care Copayment Act of 2000 (Pub. L. 106–294, October 12, 2000, 114 Stat 1038, codified at 18 U.S.C. 4048).

DATES: This rule is effective on October 3, 2005. We will not implement the provisions of this rule until 30 days after we have given notice of these rules to inmates in our custody, as required by 18 U.S.C. 4048(i).

ADDRESSES: Rules Unit, Office of General Counsel, Bureau of Prisons, 320 First Street, NW., Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT: Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307–2105.

SUPPLEMENTARY INFORMATION: Under the Federal Prisoner Health Care Copayment Act of 2000 (Pub. L. 106–294, October 12, 2000, 114 Stat 1038, codified at 18 U.S.C. 4048) (Act), the Bureau of Prisons (Bureau) may assess and collect a fee for health care services provided in connection with certain kinds of inmate health care visits. In this document, we finalize our proposed rule which was published on October 10, 2002 (67 FR 63059) describing procedures we will follow for charging inmates health service fees for certain kinds of health care services.

Response to Comments

We received 42 comments on our proposed rules. One commenter supported the rule. Eight of the comments were copies of one form letter, and another thirteen comments were copies of a second form letter. These and the other twenty commenters raised identical or similar issues. We will therefore address each issue raised.

The Fee Will Unduly Burden Family Members of Inmates

Four commenters expressed concern that the fee would unduly burden family members of inmates.

These comments failed to specify how family members of inmates would bear the ''burden'' of health service fees. If an inmate is classified as indigent and has no funds with which to pay the fee, no fee will be imposed, even though the inmate will still receive necessary health services. There is no apparent cost, therefore, to the inmate's family, who are not required to replenish the inmate's account for the purpose of paying health service fees.

The $2 Fee Is Too High

Twenty-six commenters felt that the $2 fee amount is too high for inmates. One commenter suggested that, since the statute requires that the fee be ''not less than $1.00,'' the fee should be only $1 instead of $2.

The Committee Report accompanying the Act states that ''[t]he amount of the fee is to be determined by the Director of the Bureau of Prisons through regulation.'' *H.R. Rep. No.* 106–851, at 12 (2000). Determination of the fee amount is in the Director's discretion. The Director has determined that a $2 fee is reasonable and is the smallest fee practicable when accounting for the technicalities of processing fees collected for health services.

The Bureau had initially considered a $10 fee. However, when determining the fee amount, the Bureau surveyed amounts charged by states adopting similar policies. Most states that charge a fee for health services impose between $3 and $10 for an inmate-initiated visit, such as Arizona (*Ariz. Rev. Stat.* § 31–161 (2003)), New Hampshire (*N.H. Rev. stat. Ann.* § 622:31–a (2003)), California (*Cal. Penal Code* § 5002.5 (2003)), Delaware (*Del. Code Ann.* tit.1, § 6536 (2003)), Maryland (*Md. Code Ann.*, Corr. Serv. § 2–118 (2003)), Ohio (*Ohio Rev. Code Ann.* § 5120.56 (2002)), and North Dakota (*N.D. Cent. Code* § 12–44.1–12.1 (2003)). In fact, the Bureau's fee is less than the majority of state fees charged for similar purposes.

One commenter recommended that we allow one inmate-initiated health care visit per month with no fee to defray the impact of the fee. This suggestion misunderstands the intent of the rule. Outside of institutions, individuals are not permitted one free health care visit per month. We intend this rule to more accurately reflect life outside the institution, thereby encouraging inmate fiscal responsibility.

Administrative Costs Outweigh Fee Income

Nine commenters argued that the cost to the Bureau of recordkeeping and transferring funds related to the health service fee outweighs the savings resulting from decreased sick-call visits through fee imposition.

The purpose of the rules is to decrease inmate misuse of health services and to encourage fiscal responsibility, not to increase Bureau funding. Any money gained through fees will not be retained by the Bureau. 18 U.S.C. 4048(g)(2) indicates that 75% of amounts collected must ''be deposited in the Crime Victims Fund established under section 1402 of the Victims of Crime Act of 1984 (42 U.S.C. 10601)'' and the remaining 25% must ''be available to the Attorney General for administrative expenses incurred in carrying out this section.'' The 25% reserved for administrative expenses under this subsection goes towards administrative costs associated with dispensing fee amounts to the Crime Victims Fund, and is not kept by the Bureau.

Also, among States and localities that have imposed these fees, reductions in sick call visits from 16 to 50 percent have been realized. In a report included with the legislative history of the Act, the GAO concluded that use of a health care co-payment fee system would reduce the number of unnecessary medical visits in the Federal prison system, perhaps reducing overall visits by as much as 25 percent. *H.R. Rep. No.* 106–851, at 6 (2000), referencing *Federal Prisons: Containing Health Care Costs for an Increasing Inmate Population*, No. GAO/T GGD 00 112, at 3 (April 6, 2000).

Further, according to the legislative history of the Act, the Congressional Budget Office (CBO) expects that imposing such fees would reduce the demand for health care services from Federal prisoners. CBO determined that the reduction in demand would result in possible net savings of up to $5 million annually over the 2001–2005 period, assuming that future appropriations are reduced to reflect the lower health care costs. *H.R. Rep. No.* 106–851, at 9 (2000).

Administrative Process Ineffective to Contest Fee

One commenter felt that the administrative remedy process is ineffective (because of length of time required and the nature of medical problems) to contest a $2 health service fee.