(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 10 mg per kilogram (/kg) daily; or 20 mg/kg on the initial day of treatment, followed by 10 mg/kg daily.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: May 27, 2003.

Steven F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–14678 Filed 6–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Injectable or Implantable Dosage Form New Animal Drugs; Carprofen

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 once daily, 2-milligram-per-pound dosage of carprofen solution, by subcutaneous injection, for the relief of pain and inflammation associated with osteoarthritis in dogs.

DATES: This rule is effective June 11, 2003.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail mberson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed a supplement to NADA 141–199 for RIMADYL (carprofen) Injectable used for the relief of pain and inflammation associated with osteoarthritis in dogs. The supplemental NADA provides for veterinary prescription use of a once daily, 2-milligram-per-pound dosage of carprofen solution by subcutaneous injection. The supplemental application is approved as of March 25, 2003, and the regulations are amended in 21 CFR 522.312 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 Dockets Management Branch (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 Cosmetics Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning March 25, 2003.

The agency has determined under § 25.33(d)(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 OR 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 522.312 is amended by revising (d)(1) to read as follows:

§ 522.312 Carprofen.

* * * * *

(d) * * *

(1) *Amount.* 2 mg/lb (4.4 mg/kg) body weight once daily or 1 mg/lb (2.2 mg/kg) twice daily, by subcutaneous injection.

* * * * *

Dated: May 29, 2003.

Steven D. Vaughn,

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

[FR Doc. 03–14544 Filed 6–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 601

[Docket No. 91N–0278]

New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations to correct certain errors that were incorporated into the regulations. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective June 11, 2003.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA has discovered certain errors that were inadvertently included in the agency's codified regulations for part 601 (21 CFR part 601). In the **Federal Register** of December 11, 1992 (57 FR 58942), we published a final rule that, among other things, established subpart E of part 601, which encompasses §§ 601.40 through 601.46. Currently, § 601.43(a) refers to § 601.40, instead of the correct § 601.41; § 601.43(b) refers to § 601.40, instead of the correct § 601.42. Accordingly, we are amending § 601.43(a) by replacing the incorrect reference to § 601.40 with a reference to § 601.41, and we are amending § 601.43(b) by replacing the incorrect reference to § 601.40 with a reference to § 601.42. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment is nonsubstantive.

List of Subjects in 21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 601 is amended as follows:

PART 601—LICENSING

■ 1. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356B, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec. 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

§ 601.43 [Amended]

■ 2. Section 601.43 *Withdrawal procedures* is amended in the introductory text of paragraph (a) by removing ''§§ 601.40 and 640.42'' and adding in its place ''§ 601.41 or § 601.42'', and in paragraph (b) by removing ''§ 601.40 or § 601.41'' and adding in its place ''§ 601.41 or § 601.42''.

Dated: June 4, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–14621 Filed 6–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 31, and 602

[TD 9061]

RIN 1545–BB55

Automatic Extension of Time To File Certain Information Returns and Exempt Organization Returns

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains temporary regulations providing an automatic extension of time to file certain information returns and exempt organization returns. The temporary regulations remove the requirement for a signature and an explanation to obtain an automatic extension of time to file these returns. The temporary regulations affect taxpayers who are required to file certain information returns and/or exempt organization returns and need an extension of time to file. The text of the temporary regulations also serves as a portion of the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on June 11, 2003.

Applicability Date: For dates of applicability for these regulations, see §§ 1.6081–8T, 1.6081–9T, and 31.6081(a)–1T(d).

FOR FURTHER INFORMATION CONTACT: Charles A. Hall, (202) 622–4940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

These temporary regulations are being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collection of information contained in these regulations has been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget under OMB control number 1545–1840. Responses to this collection of information are required by the IRS for taxpayers to obtain a benefit (an automatic extension of time to file certain information or exempt organization returns).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

For further information concerning this collection of information, and where to submit comments on the collection of information and the accuracy of the estimated burden, and suggestions for reducing this burden, please refer to the preamble to the cross-referencing notice of proposed rulemaking published in the Proposed Rules section of this issue of the **Federal Register**.

Books and records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

This document contains amendments to 26 CFR parts 1, 31, and 602 under section 6081 of the Internal Revenue Code. Section 6081(a) provides that the Secretary may grant a reasonable extension of time for filing any return, declaration, statement, or other document required by Title 26 or by regulations. Except in the case of taxpayers who are abroad, no such extension shall be for more than 6 months. The regulations under section 6081 provide specific rules taxpayers must follow to request an extension of time to file Federal tax returns.

Under the generally applicable rule, a taxpayer must submit an application for the extension on or before the due date of the return. The application must be in writing, must be properly signed by the taxpayer or his duly authorized agent, and must clearly set forth the particular tax return for which the extension of the time for filing is desired and a full recital of the reasons for requesting the extension. These rules apply to all returns other than those for which the regulations provide special rules. In addition, the Employment Tax Regulations provide rules for employers to obtain an extension of time to file the Social Security Administration copy of Forms W–2 and W–3. Under those rules, the request must contain a concise statement of the reasons for requesting the extension.

Explanation of Provisions

Information Returns

Filers and transmitters of information returns on Form 1099 (series), 1098 (series), 5498 (series), W–2 (series), W–2G, 1042–S, and 8027 can obtain an extension of time to file these information returns by submitting a signed paper Form 8809, ''Request for Extension of Time to File Information Returns.'' The extensions are most often for a period of 30 days. Filers and transmitters may thereafter request an additional 30-day extension. The extensions apply only to the filing with the government. The filer or transmitter is still required to provide statements to the recipients by the date specified in the Code or the regulations.

Currently, in compliance with the regulations, Form 8809 requires a signature and asks for an explanation of the reasons for the request for an extension. In current practice, however, the explanation is not a determining factor for the initial extension. If the filer supplies the name, address, Employer Identification Number, tax year, and type of form(s), the initial extension is routinely granted. An extension beyond the initial 30-day period will not be granted, however, unless the filer provides a detailed explanation.

These temporary regulations allow filers and transmitters to request an automatic 30-day extension of time to file without having to sign Form 8809 and provide an explanation. An explanation and a signature are required if filers and transmitters need additional time to file after receiving the automatic 30-day extension. These regulations also permit employers to obtain an extension of time to file the Social Security Administration copy of Forms W–2 and W–3 without providing a statement of the reasons for requesting the extension.