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 carprofen solution for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs. The supplemental application is approved as of April 2, 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 April 2, 2003.

The agency has determined under 21 CFR 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 paragraphs (d)(1) and (d)(2) 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. For the control of postoperative pain, administer approximately 2 hours before the procedure.

(2) *Conditions of use*. For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries.

* * * * *

Dated: August 1, 2003.

Bernadette Dunham,

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

[FR Doc. 03–20997 Filed 8–15–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

Ophthalmic Devices

CFR Correction

In Title 21 of the Code of Federal Regulations, Parts 800 to 1299, revised as of April 1, 2003, in § 886.1500, on page 456, paragraph (b) is added to read as follows:

§ 886.1500 Headband mirror.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[FR Doc. 03–55524 Filed 8–15–03; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 4443]

Documentation of Nonimmigrants Under the Immigration and Nationality Act, as Amended: Automatic Visa Revalidation

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department is adopting as final an interim rule published in the **Federal Register** on March 7, 2002, amending the regulation pertaining to Automatic Visa Revalidation, which was effective on April 1, 2002.

EFFECTIVE DATE: August 18, 2003.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Harper, Legislation and Regulations Division, Visa Services, Department of State, Washington, D.C. 20520–0106, (202) 663–1221, e-mail (*harperb@state.gov*) or fax at (202) 663–3898.

SUPPLEMENTARY INFORMATION: The Department published an interim rule, Public Notice 3938 at 67 FR 45, March 7, 2002, with a request for comments, amending part 41 of Title 22 of the Code of Federal Regulations.

Why Was This Done?

The rule was proposed primarily because of the need for greater screening of visa applicants in light of the events of September 11, 2001. The rule was discussed in detail in Public Notice 3938, as were the Department's reasons for the other changes to the regulations. This final rule adopts the interim rule without change.

What Did The Interim Rule Do?

The interim rule limited the privilege of automatic revalidation of visas in two respects: first, the privilege is no longer available to persons who choose to apply for a new visa while traveling temporarily to an area covered by the automatic revalidation privilege; and second, it is no longer available to nationals of countries that are state sponsors of terrorism, regardless of whether such nationals apply for a new visa while outside the United States or not. In essence, the addition of ''applying for a visa while abroad'' as a bar against automatic revalidation was undertaken to protect against the possibility that the visa applicant will be found ineligible but will have returned to the United States using the automatic revalidation privilege while the visa application was pending. The bar against nationals of states that have