

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

been found to sponsor terrorism was added for the additional reason that such nationals have become subject to heightened standards of review before visa issuance.

Analysis of Comments

The proposed rule was published with a request for comments on March 11, 2002 (67CFR45). The comment period closed May 7. The Department received roughly 300 comments, half or more of which were verbatim in full or in part with a sample proposed response that circulated through the foreign student community. Most of the first half of the letters (see "other factors noted, below") quoted the sample proposed response in full; many used only one or two paragraphs from it. The Department therefore is responding to the comments collectively, by subject matter.

Ineffectiveness and Unfairness; Inconvenience

The sample proposed response and many of the letters drawing upon it claimed the following:

1. The amended requirement would not deter the entry of terrorists because, in the new circumstances, any terrorists already in the United States would simply stay here, rather than going to a neighboring country for a new visa. Moreover, they would supply false information if they did go abroad and applied for a visa.

2. This unfairly penalizes the innocent while doing nothing against evil-doers.

3. It is "not in compliance with U.S. fundamental interests—handicapping the mutual beneficial culture, economic and personnel exchanges between the U.S. and other countries."

Other Factors Noted

The majority of the other half of letters included one or more of the above viewpoints in addition to the following:

Most of their homes (in their homelands) are very far from a U.S. consulate and it takes much longer to obtain a visa there than in Canada or Mexico. (All, or almost all, of the commenters were from China, India or the Philippines.) Thus, if they cannot apply for a visa in Canada or Mexico without risking their re-admission in case of delays, they will simply have to forego any trips home to see their families. Some closed with the suggestion that, moreover, if they weren't limited to single-entry, six-month visas, they wouldn't need the automatic revalidation so why do we

not simply give them more favorable visas to begin with.

They resent the implication that they, as lawful temporary (but long-term) residents (nonimmigrant students and workers) are a threat to the United States.

They have to travel abroad for "x" reasons (international meeting, study, research, business) and will not have time to get a visa while at the meeting or whatever. This means that if they have not obtained a reentry visa in Mexico or Canada before keeping that commitment, they will have to forego the activity for which they wish to travel abroad (finishing their studies/research abroad, presenting their paper, etc.), or simply go home thereafter, rather than finishing their employment/degree here. The latter course will also risk the loss of their apartments, cars, etc., that they will have left here while on that foreign trip. Left implicit was the idea that if the prior rule applied, they would obtain another visa in Canada/Mexico before travelling to wherever else and not have to face such a harrowing choice.

Department's Response

Although sympathetic to the concerns of the commenters, the Department must note that the privilege of automatic revalidation, instituted some years ago as a convenience both to the travelers and to our consular posts, is just that—a privilege. It is not a right. It is intended primarily to recognize that persons lawfully in the United States may have occasion to cross into and out of Canada or Mexico for brief, casual visits or even in direct transit between one part of the United States and another. In cases involving aliens who are within their authorized stay in the United States but whose visas have expired, it is not always practicable for them to apply for and obtain a new visa to reenter the United after such a departure. Thus a provision was made to consider their visas automatically revalidated for purposes of facilitating such brief trips. Automatic revalidation also became a vehicle for aliens whose visas had expired and who wanted to travel to more distant countries not within the scope of the automatic revalidation regulation (e.g., in Asia or Europe). Under the old automatic revalidation regulation, such aliens could leave the United States temporarily and apply for a new visa in a country such as Mexico or Canada that was covered by the automatic revalidation regulation. This was not the original intent of the regulation, however.

These are difficult and different times, and certain conveniences must be foregone. We are preserving the availability of automatic revalidation for its original fundamental purpose, which is to recognize and facilitate short-term cross-border travel. By eliminating the possibility of automatic revalidation for persons who apply for a visa while outside the United States, we are merely eliminating a use of the regulation that was not central to its purpose. At the same time, however, we are reflecting the new security environment, in which visa processing times are longer and favorable outcomes are significantly less certain.

For those whose complaint was that they wouldn't need that automatic revalidation provision if we would issue them more than 6 month/one entry visas in the first place, we can only note that such matters are governed by reciprocity as well as national security considerations. The question of longer validity periods or multiple versus single entry visas does not even arise if an alien's government does not issue longer validity, multiple entry visas to U.S. citizens for the same purpose of entry.

Preclearance Suggestion

A few letters took a different approach. They suggested that all of the above problems could be resolved if the need for special screening could be met by applying for preclearance (in a timely fashion) before going to Canada or Mexico. That is, use some mechanism for such intending traveler/visa applicants to get security cleared here in the United States in advance of their trip to Canada or Mexico to apply for the visa.

Department's Response

The Department concluded that this proposal is not practicable for a number of reasons, such as the absence of any mechanism in the United States for processing such requests in advance and the lack of resources to establish one. More important is the fact that the time frame for responses to clearance requests is too fluid for realistically estimating when to begin such a process. Therefore it cannot be implemented.

Regulatory Analysis and Notices

Since the final rule is unchanged from the interim rule, and because none of the public comments have called them into question, the Department reiterates the regulatory analysis and notices published in 67 FR 45 on March 7, 2002.

List of Subjects in 22 CFR Part 41

Aliens, Passports and visas.

■ Accordingly, the Department of State adopts as final the interim rule published on March 7, 2002 (67 FR 10322) that revised 22 CFR 41.112(d).

Dated: June 26, 2003.

Maura Harty,

*Assistant Secretary for Consular Affairs,
Department of State.*

[FR Doc. 03-21070 Filed 8-15-03; 8:45 am]

BILLING CODE 4710-06-P

DEPARTMENT OF STATE**22 CFR Part 42**

[Public Notice 4446]

Documentation of Immigrants Under the Immigration and Nationality Act, As Amended: Electronic Petition for Diversity Immigrant Status

ACTION: Interim rule with request for comments.

SUMMARY: In this rule the Department changes the manner in which aliens may petition for the opportunity to participate in the Diversity Visa Program from a standard mail-in system, to an entirely electronic system that will utilize a specifically designated Internet website. This rule also makes minor technical and editorial changes to the existing rule for the purpose of greater clarity, uniformity and precision. The Department is implementing the new electronic system in order to make the process less prone to fraud, improve efficiency in the diversity visa petition process and significantly reduce the cost to the Government of the process. When the rule is published aliens petitioning to participate in the diversity visa program will be required to submit their petition to the Department exclusively via electronic means.

DATES: This rule becomes effective on August 18, 2003. Written comments must be received on or before October 17, 2003.

ADDRESSES: Written comments may be submitted to the Chief, Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20520-0106, by fax to 202-663-3898, or by e-mail to VisaRegs@state.gov.

FOR FURTHER INFORMATION CONTACT: Ron Acker, Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20520-0106, 202-663-0102.

SUPPLEMENTARY INFORMATION:

What Is the Diversity Visa Program?

The Diversity Visa Program is an annual visa program administered by the Department of State pursuant to section 203(c) of the Immigration and Nationality Act (INA), 8 U.S.C. 1153(c). Aliens from eligible countries (as determined by the Department of Homeland Security) petition the Department for the opportunity to apply for one of 50,000* immigrant visas made available each year pursuant to section 201(e) of the INA, 8 U.S.C. 1151(e) (note that section 201(e) actually provides for 55,000 visas, however, the Nicaraguan Adjustment and Central American Relief Act of 1997 (NACARA), Title II of P.L. 105-100, stipulated that 5,000 of the immigrant visas made available under section 201(e) would be set aside each year for aliens eligible to adjust their status to that of lawful permanent resident under that Act*). The Department selects and rank orders petitions at random from among those that meet all of the prescribed petition requirements. Aliens whose petitions are selected may then apply for visas in rank order on a first come, first served basis until all of the 50,000* visas for the fiscal year for which the petitions have been selected are issued, or the fiscal year ends, whichever comes first.

What Is the Current Petition Procedure for the Program?

Since the inception of the Diversity Visa Program, the Department has required that all petitions for acceptance of an alien into the program be submitted by mail during a thirty-day period in the fiscal year preceding the fiscal year for which petitioners seek eligibility for the program. To date, submission by any means other than regular mail has been prohibited.

According to the existing rule, individual petitioners have been instructed to include certain information about themselves and their family members on a sheet of paper and to submit that document, signed, along with signed photographs of themselves and family members to the Department at a specific mailing address. Petitions without the required information or signatures and those received before or after the dates of the mail-in period have been automatically disqualified from consideration. Further, the statute authorizing the program permits only one petition submission per applicant. Persons submitting multiple petitions also are disqualified from participation in the program. No fee has been charged at the time of submission of the petition, but recipients of diversity immigrant visas have been required at the time of

visa application to pay an additional processing fee beyond that paid by other classes of immigrant visa recipients.

How Will This Rule Change the Petition Procedure?

When this rule becomes effective, alien petitioners for the Diversity Visa Program will no longer be permitted to submit a petition by mail. Instead, the Department will require that all petitions be submitted to it in an electronic format, using an Internet website dedicated specifically to the submission and receipt of Diversity Visa Program petitions. The website will have contained in it a standard petition form which the petitioner, or someone acting for the petitioner, must fill out on-line and send electronically to the Department at a web address. The person completing the petition form will also be required to attach to the electronic petition individual digital photographs of the petitioner and the petitioner's spouse and unmarried children under 21 who will be seeking to accompany or follow to join the petitioner should the petitioner receive a diversity immigrant visa. The photographs will have specific requirements as to size, composition and quality. Fees will be handled as they are under the current rules for diversity program petitions. Because the petition must be submitted electronically, the current requirement that the petition and photographs be signed, is, necessarily, being eliminated.

Why Is the Department Changing the Petition Process in this Manner?

There are three principal reasons the Department believes an electronic petition process is preferable to the existing mail-in process.

Anti-fraud benefits: The Department believes that the electronic petition process will help eliminate the submission of multiple petitions, prohibited under INA section 204(a)(1)(I). Currently, despite the fact that only 50,000* visas are available each year, many millions of petitions are submitted. The Department uses its limited resources to crosscheck for multiple submissions and create records for only the number of correctly completed petitions sufficient to ensure a pool of visa applicants that will be large enough to guarantee use of all the visas. That number is only a small percentage of the overall total of petitions submitted. Therefore, the likelihood of an alien petitioner of being caught submitting more than one petition is much less than it would be if information from all of the petitions could be entered automatically into the