In addition to the meeting discussed above and other informal communications that FDA has had with industry, industry associations, and Congress, FDA received a petition for stay of action requesting that the relevant provisions of the final rule be stayed until October 1, 2001. The agency also received a petition for reconsideration from the Small Business Administration (SBA) requesting that FDA reconsider the final rule and suspend its effective date based on the projected severe economic impact it would have on over 4,000 small businesses. The petitions argued that the requirement for a written agreement in § 203.3(u) is unreasonable because manufacturers are not willing to enter such agreements with the majority of smaller distributors. The petitions also asserted that authorized wholesalers are not now able and could not provide, at a reasonable cost, an identifying statement to their unauthorized distributor customers that meets the requirements of § 203.50 of the final rule. The SBA petition asserted that, if the effective date of the final rule is not stayed, drug products now in the inventory of wholesalers will have to be cleared and new orders will have to cease or be severely limited in order to comply with the final rule's December 4, 2000 effective date, with corresponding disruptions in the distribution of drugs possible by summer, 2000.

B. Distribution of Blood Derivatives by Health Care Entities

Since the time of the proposed rule, FDA has received 2 letters, one from a large blood center and the other from an association representing the blood center industry, and has held several meetings to discuss the implications of the regulations on blood centers that distribute blood derivative products and provide health care as a service to the hospitals and patients they serve. The blood center industry asserts that the regulations and, particularly the definition of ''health care entity,'' will severely inhibit their ability to provide full service care to the detriment of client hospitals and the patients they serve, and may disrupt the distribution of these products to the public. The agency has also received a letter from a member of Congress on this issue. Although the agency was aware of this issue at the time the final rule was published, we believed that application of § 203.3(q) to blood centers would not result in a disruption in the distribution of blood derivative products. However, comments and information provided by representatives of the blood center industry have persuaded us that the final rule could disrupt the availability of blood derivative products to the public.

C. Partial Delay of the Effective Date

Based on the concerns expressed by industry, industry associations, and Congress about implementing §§ 203.3(u) and 203.50 by the December 4, 2000, effective date, the agency has decided to delay the effective date for those sections of the final rule until October 1, 2001. Additionally, the agency has decided to delay the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities, until October 1, 2001. All other provisions of the rule will become effective on December 4, 2000. This action should not be construed to indicate that FDA necessarily agrees with or has made decisions about the substantive arguments made in the petitions and other submissions related to implementation of §§ 203.3(u) and 203.50 or § 203.3(q), as it applies to wholesale distribution of blood derivatives by health care entities.

III. Reopening of the Administrative Record

The agency believes that providing additional time before these are to become effective is appropriate to permit the agency to obtain more information about the possible consequences of implementing these provisions, to further evaluate the issues involved, and to seek a legislative resolution to these issues, if necessary. Therefore, the agency is reopening the administrative record to receive additional comments on these provisions from interested individuals. Regarding §§ 203.3(u) and 203.50, the agency is especially interested in gaining further insight into the potential impact of the provisions on the wholesale distribution system generally, and on the ability of smaller pharmacies and other prescription drug retailers to obtain prescription drugs. In addition, the agency is seeking comments on the potential economic impact of the provisions on smaller wholesale distributors that are not authorized distributors of record. Regarding § 203.3(q), the agency also invites comment on the economic and public health impact of including full service blood centers under the definition of ''health care entity,'' thereby prohibiting the wholesale distribution of blood derived products by such entities.

Interested persons may submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written comments regarding this proposal by July 3, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This action is being taken under FDA's authority under 21 CFR 10.35(a). The Commissioner of Food and Drugs finds that this delay of the effective date is in the public interest.

Dated: April 26, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–10920 Filed 4–28–00; 12:34 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name and address for Global Pharmaceutical Corp.

DATES: This rule is effective May 3, 2000.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Global Pharmaceutical Corp., Castor and Kensington Aves., Philadelphia, PA 19124, has informed FDA of a change of sponsor's name and address to IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor's name and address.

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 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for ''Global Pharmaceutical Corp.'' and by alphabetically adding an entry for ''IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544''; and in the table in paragraph (c)(2) in the entry for ''000115'' by removing the sponsor name and address and by adding their place ''IMPAX Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.

Dated: April 24, 2000.

Claire M. Lathers,

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

[FR Doc. 00–10932 Filed 5–2–00; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 560

Iranian Transactions Regulations: Licensing of Imports of, and Dealings in, Certain Iranian-Origin Foodstuffs and Carpets

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule; amendments.

SUMMARY: The Treasury Department is amending the Iranian Transactions Regulations to add general licenses authorizing the importation into the United States of, and dealings in, certain Iranian-origin foodstuffs and carpets and related transactions.

EFFECTIVE DATE: April 28, 2000.

FOR FURTHER INFORMATION CONTACT: Steven I. Pinter, Chief of Licensing (tel.: 202/622–2480), Barbara C. Hammerle, Deputy Chief Counsel (tel.: 202/622–2410), Office of Foreign Assets Control, U.S. Treasury Department, Washington, DC 20220.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

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Background

On March 17, 2000, Secretary of State Madeleine K. Albright announced that economic sanctions against Iran would be eased to allow Americans to purchase and import carpets and food products such as dried fruits, nuts, and caviar from Iran. To implement this policy, the Treasury Department's Office of Foreign Assets Control (''OFAC'') is amending the Iranian Transactions Regulations, 31 CFR part 560 (the ''Regulations''), to authorize, by general license, the importation into the United States of, and dealings in, certain Iranian-origin foodstuffs and carpets and related transactions.

Section 560.534(a) of this final rule authorizes the importation into the United States of Iranian-origin foodstuffs intended for human consumption that are classified under chapters 2–23 of the Harmonized Tariff Schedule of the United States (''HTS''). Items that are classified in chapters 2–23 of the HTS that are not foodstuffs intended for human consumption are not authorized for importation into the United States by this section. This final rule also authorizes the importation into the United States of Iranian-origin carpets and other textile floor coverings and carpets used as wall hangings that are classified under chapter 57 or heading 9706.00.0060 of the HTS. Items that are classified under heading 9706.00.0060 (''Antiques of an age exceeding one hundred years/Other'') that are not carpets and other textile floor coverings or carpets used as wall hangings are not authorized for importation into the United States by this section.

Section 560.534(b) of this rule authorizes U.S. persons, wherever located, to engage in transactions or dealings in such Iranian-origin foodstuffs and carpets, provided that such transactions or dealings do not involve a prohibited exportation to Iran or the Government of Iran. Section 560.534(c) sets forth the effect of this rule on open and closed enforcement actions initiated by the U.S. Government prior to the effective date of this final rule.

Transactions ordinarily incident to the transactions authorized in § 560.534 and necessary to give effect thereto also are authorized as set forth in § 560.405. Section 560.405 is amended to exclude from the scope of permitted incidental transactions letter of credit services relating to transactions authorized in § 560.534. See § 560.405(e). Those letter of credit services that are authorized are set forth separately in § 560.535. Forms of financing other than letters of credit are permitted as incidental transactions as set forth in § 560.405, provided that such forms of financing do not involve a debit or credit to an account of a person in Iran or of the Government of Iran maintained on the books of a U.S. depository institution. See § 560.534(d). Brokering services relating to transactions authorized by this final rule also are authorized. See § 560.535(c). Examples of transactions permitted under this final rule are set forth in §§ 560.534(e) and 560.535(e).

Technical changes are made to § 560.405, to clarify that loading of licensed cargo in Iran is a permitted incidental transaction, and to § 560.524, to clarify that the importation into the United States of qualifying household goods and personal effects is permitted regardless of the time elapsed since the importer's arrival in the United States from Iran.

Because the Regulations involve a foreign affairs function, Executive Order 12866 and the provisions of the Administrative Procedure Act (5 U.S.C. 553) (the ''APA'') requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.