

The proposed consent order has been placed on the public record for sixty (60) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreements and the comments received and will decide whether it should withdraw the argument or make the proposed consent order final.

By accepting the proposed consent order subject to final approval, the Commission anticipates that the competitive problems alleged in the complaint will be resolved. The purpose of this analysis is to facilitate public comment on the proposed consent order, including the proposed sale of the Avecor pump assets to Baxter, in order to aid the Commission in its determination of whether to make the proposed consent order final. This analysis is not intended to constitute an official interpretation of the proposed consent order, nor is it intended to modify the terms of the proposed consent order in any way.

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 99-7210 Filed 3-23-99; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Ricky Ray Hemophilia Relief Fund Act of 1998, Procedures for Filing Petitions for Payment

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) announces procedures for filing Notices of Intent to File Petitions for payment under the newly enacted Ricky Ray Hemophilia Relief Fund Act of 1998 ("the Act"). Although the Act became law on November 12, 1998, no funds have been appropriated either for the payment of awards to petitioners or for the administrative costs to HHS for operating this new program. Nevertheless, the Act states that HHS shall first establish procedures to implement the Act within 120 days of its enactment. We are establishing as a first procedure under the Act the opportunity for individuals to file Notices of Intent to File Petitions, which may lead to later filings of full petitions and determinations on those petitions if funding is appropriated to operate the

program and to pay awards. The timely filing of a Notice of Intent to File a Petition will meet a petitioner's obligation to file within the statutory limitations period for seeking payment from the Ricky Ray Hemophilia Relief Fund. Again, since no funds have been appropriated for this program, submitting a Notice of Intent to File a Petition allows a petitioner to record his or her intent to seek payment should Congress appropriate funds in the future.

ADDRESSES: Notices of intent meeting the requirements described below shall be sent to: Ricky Ray Program Office, Bureau of Health Professions, Room 8-05, 5600 Fishers Lane, Rockville, Maryland 20857.

DATES: The procedures established by this noticed shall take effect on April 23, 1999.

FOR FURTHER INFORMATION CONTACT: Neil Sampson, Deputy Associate Administrator for Health Professions, Health Resources and Services Administration, Room 805, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-2330.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Act provides for compassionate payments with regard to certain individuals with blood-clotting disorders, such as hemophilia, who contracted human immunodeficiency virus (HIV) due to contaminated antihemophilic factor within specified time periods. Section 101 of the Act establishes in the Treasury of the United States a trust fund known as the Ricky Ray Hemophilia Relief Fund. The Act authorizes appropriations to the Fund of \$750,000,000. To date, no appropriations have been made for the Fund. In addition, no appropriations have been made for the administrative costs to HHS for operating this program.

Section 102(a) of the Act provides that, if there are sufficient amounts in the Fund to make each payment, the Secretary shall make a single payment of \$100,000 to any individual who has an HIV infection and who is described in one of the following paragraphs:

(1) The individual has any form of blood-clotting disorder, such as hemophilia, and was treated with antihemophilic factor at any time during the period beginning on July 1, 1982, and ending on December 31, 1987.

(2) The individual is (A) the lawful spouse of an individual described in paragraph (1) or (B) the former lawful spouse of an individual described in paragraph (1) and was the lawful spouse of the individual at any time after a

date, within the period described in paragraph (1) on which the individual was treated as described in paragraph (1) and can assert reasonable certainty of transmission of HIV from such individual.

(3) The individual acquired HIV infection through perinatal transmission from a parent who is an individual described in paragraph (1) or (2).

Section 103 provides for the payment to certain survivors if the individuals listed in section 102 are deceased when that payment is to be made. If the individual eligible for payment dies before filing a petition, a survivor may file a petition on his or her behalf (section 103(c)(2)(B) of the Act).

Although an attorney or other representative is not required, petitioners may engage the services of an attorney or other agent to render services in connection with the petition. No such attorney or agent may receive for services rendered more than five percent of an payment made under the program (section 107 of the Act).

For the full text of the Act, individuals may consult the World Wide Web site of the Library of Congress at "<http://thomas.loc.gov>" and seek Public Law 105-369, or they may seek the public law from a law library.

II. Statutory Procedures

Under section 105 of the Act, petitions seeking payment from the Ricky Ray Hemophilia Relief Fund must be filed by eligible petitioners within 3 years after the date of enactment of the Act, i.e., by November 11, 2001. Accordingly, even though no appropriations have been made for payment with respect to petitioners or for administration of the program, we are establishing the following first procedures to implement the Act.

III. Filing of Notice of Intent

An eligible individual may submit a Notice of Intent to File a Petition stating an intent to file a full petition when appropriate. The Notice of Intent shall include the following:

(1) The name of the petitioner, with current address and phone number.

(2) The name, address, and phone number of the petitioner's attorney of record or other representative for the petition, if any.

The notice of intent shall be sent to: Ricky Ray Program Office, Bureau of Health Professions, Room 8-05, 5600 Fishers Lane, Rockville, Maryland 20857.

On receipt of the Notice of Intent to File a Petition, we will respond with an acknowledgment reflecting a case number assigned to the filing.

Thereafter, petitioner must advise the Department of any change of address, phone number, or attorney of record or other representative. We will not further process a Notice of Intent to File a Petition if we are unable to contact the petitioner or her/his attorney or other representative in the future because of a change in such information of which we were not informed. New name, address, phone number(s) or attorney or other representative information should be sent to the same addressee as will receive Notices of Intent to File a Petition.

The date of receipt of the Notice of Intent will be viewed as the date of filing for purposes of the 3-year time limit on filing petitions (section 105 of the act). The Notice of Intent will not activate Departmental consideration beyond sending an acknowledgment of its receipt since processing and consideration commence on the filing of an actual petition. The sending of the acknowledgment in no way implies that the petitioner has been determined to be eligible for a payment. The review period described in section 103(d) of the Act will begin on receipt of a full petition containing all information to be specified in future instructions. All filings are confidential and will be used only for authorized purposes.

Should funds be appropriated for the administrative costs of the program and for the payment of successful petitions, we will advise those who submit Notices of Intent of the content, format, and deadlines for future submissions related to the petition.

Dated: March 10, 1999.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 99-7221 Filed 3-23-99; 8:45 am]

BILLING CODE 4165-15-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-1036]

Vale Chemical Co., Inc., et al.; Withdrawal of Approval of 13 New Drug Applications and 1 Abbreviated New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 13 new drug applications (NDA's) and 1 abbreviated new drug application (ANDA). The basis for the withdrawals is that the holders of the applications have repeatedly failed to file required annual reports for these applications.

EFFECTIVE DATE: March 24, 1999.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: The holders of approved applications to

market new drugs or antibiotics for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81).

In the **Federal Register** of December 2, 1998 (63 FR 66549), FDA offered an opportunity for a hearing on a proposal to withdraw approval of 13 NDA's and 1 ANDA because the firms had failed to submit the required annual reports for these applications.

Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101-8299, notified the agency that they no longer market the products for NDA's 50-088, 50-129, 50-189, 50-197, 50-305, and 50-319. Wyeth-Ayerst did not request a hearing and submitted a formal request for the agency to withdraw approval of the NDA's for these products.

The holders of the other eight applications did not respond to the notice of opportunity for a hearing. Failure to file a written notice of participation and request for a hearing as required by 21 CFR 314.200 constitutes an election by the applicant not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products. Therefore, the Director, Center for Drug Evaluation and Research, is withdrawing approval of the applications listed in the table of this document.

Application No.	Drug	Applicant
NDA 7-112	Nisaval (pyrilamine maleate) 25 milligram (mg) Tablets	Vale Chemical Co., Inc., 1201 Liberty St., Allentown, PA 18102.
NDA 11-863	Flavihist Cough Syrup	Boyle & Co., 6330 Chalet Dr., Los Angeles, CA 90022.
NDA 50-042	Potassium Penicillin G Diagnostic Sensitivity Powder, 20,000 units	Pfizer Inc., 235 East 42d St., New York, NY 10017-5755.
NDA 50-067	Compocillin-VK Chewable Wafers	Abbott Laboratories, 100 Abbott Park Rd., Abbott Park, IL 60064.
NDA 50-088	Unipen Injection	Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101-8299.
NDA 50-121	Compocillin-VK Tablets	Abbott Laboratories.
NDA 50-122	Compocillin-V Chewable Wafers	Do.
NDA 50-129	Pen-Vee Suspension and Drops	Wyeth-Ayerst Laboratories.
NDA 50-189	Omnipen Tablets	Do.
NDA 50-197	Unipen Injection	Do.
NDA 50-305	Unipen Capsules	Do.
NDA 50-319	Omnipen Chewable Tablets	Do.
NDA 50-413	Geopen Diagnostic Susceptibility Powder	Pfizer Inc.
ANDA 87-387	Aminophylline Injection USP, 25 mg/milliliter	Pharma-Serve, Inc., 218-20 98th Ave., Queens Village, NY 11429.

The Director, Center for Drug Evaluation and Research, under section 505(e) of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 355(e)), and under authority of 21 CFR 5.82, finds that the holders of the applications

listed in the table of this document have repeatedly failed to submit reports required by § 314.81. Therefore, under