Procurement Organizations, with an expiration date of November 30, 2001.

Authority: Section 1138 of the Social Security Act (42 U.S.C. 1320b–8).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare-Hospital Insurance; Program No. 93.774, Medicare-Supplementary Medical Insurance, and Program No. 93.778, Medical Assistance Program)

Dated: July 20, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01–19438 Filed 8–2–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1638]

Alpharma, Inc.; Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) held by Alpharma, Inc. The NADA 111–637 provides for use of tylosin Type A medicated articles to make Type C medicated swine, beef cattle, and chicken feeds. Alpharma, Inc., holds NADA 46–415 that also provides for use of tylosin Type A medicated articles to make Type C medicated swine, beef cattle, and chicken feeds. Therefore, this withdrawal of approval does not require amending the animal drug regulations.

EFFECTIVE DATE: August 13, 2001.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0159.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of NADA 111–637. The NADA provides for use of tylosin Type A medicated articles to make Type C medicated swine, beef cattle, and chicken feeds. The firm requested that approval of the NADA be withdrawn because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), and further redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with 21 CFR 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 111–637 and all supplements and amendments are withdrawn, effective August 13, 2001.

Alpharma, Inc., holds NADA 46–415 that also provides for use of tylosin Type A medicated articles to make Type C medicated swine, beef cattle, and chicken feeds. Therefore, withdrawal of approval of NADA 111–637 does not require amending the animal drug regulations in 21 CFR 558.625(b)(54).

Dated: July 6, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–19463 Filed 8–2–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0262]

Draft ''Guidance for FDA Reviewers: Premarket Notification Submissions for Automated Testing Instruments Used in Blood Establishments;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for FDA Reviewers: Premarket Notification Submissions for Automated Testing Instruments Used in Blood Establishments'' dated August 2001. The draft guidance document provides an overview of the type of information FDA reviewers should expect to be included in premarket notifications submitted to the Center for Biologics Evaluation and Research (CBER) for such devices and the approach FDA reviewers should take in reviewing premarket submissions for automated instruments used for testing in blood establishments. This document, when finalized, is intended for use by establishments that manufacture blood and blood components (e.g., in testing for blood borne pathogens, blood grouping/typing, pre-transfusion compatibility, etc.).

DATES: Submit written comments on the draft guidance to ensure their adequate consideration in preparation of the final document by November 1, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for FDA Reviewers: Premarket Notification Submissions for Automated Testing Instruments Used in Blood Establishments'' dated August 2001. The purpose of a premarket notification (510(k)) submission is to demonstrate that the medical device to be marketed is substantially equivalent to a device that is already legally marketed. The draft guidance presents an overview of the type of information FDA reviewers should expect to be included in premarket notifications submitted to CBER for automated testing instruments used for testing in blood establishments, and clarifies the approach FDA reviewers should take in reviewing these types of premarket submissions. These automated testing instruments are routinely used for detection of blood borne pathogens, blood grouping/typing, and in pre-transfusion compatibility testing.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document represents the agency's current thinking on the review of premarket notification submissions for automated instruments used for testing in blood establishments. It does not create or confer any rights for or on