Dated: July 26, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–19422 Filed 8–2–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: CMS–R–227]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Research and Analytic Support for Implementing Peformance Measurement in Medicare Fee for Service; *Form No.:* CMS–R–227 (OMB# 0938–0718); *Use:* As required by the Balanced Budget Act (BBA), Section 1851(d), the Health Care Financing Administration (HCFA) needs to develop comparable performance measures for Fee For Service (FFS) Medicare. This project will enable HCFA to evaluate the effectiveness and outcomes of FFS services purchased. HCFA may potentially disseminate this information to Medicare beneficiaires so that they may make informed health care choices; *Frequency:* Biannually; *Affected Public:* Individuals or households, business or other for-profit, not-for-profit institutions, farms, Federal Government, and State, Local or Tribal Government;

Number of Respondents: 6,670;
Total Annual Responses: 6,670;
Total Annual Hours: 2,223.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: Melissa Musotto, Room: N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Julie Boughn,

Acting HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–19388 Filed 8–2–01; 8:45 am]

BILLING CODE 4120–03–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1193–NC]

Medicare and Medicaid Programs; Announcement of Applications From Hospitals Requesting Waivers for Organ Procurement Service Areas

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice announces three applications that we have received from hospitals requesting waivers from entering into agreements with their designated organ procurement organizations (OPOs), in accordance with section 1138(a)(2) of the Social Security Act. This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant these waivers.

COMMENT DATE: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 2, 2001.

ADDRESSES: In commenting, please refer to file code CMS–1193–NC. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1193–NC, P.O. Box 8010, Baltimore, MD 21244–8010.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Mark A. Horney, (410) 786–4554.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Blvd., Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–9994.

I. Background

Organ Procurement Organizations (OPOs) are not-for-profit organizations that collect human organs from hospitals and distribute them to transplant centers around the country. Qualified OPOs are designated by the Centers for Medicare & Medicaid Services (CMS) to collect organs in CMS-defined exclusive geographic service areas, according to section 371(b)(1)(E) of the Public Health Service Act (42 U.S.C. 273(b)(1)(E)) and our regulations at 42 CFR 486.307. Once an OPO has been designated for an area, hospitals in that area that participate in Medicare and Medicaid are required to work with that OPO in providing organs for transplant, according to section

1138(a) of the Social Security Act (the Act), and our regulations at § 482.45.

Section 1138(a)(1)(A)(iii) of the Act provides that a hospital must notify the designated OPO (for the service area in which it is located) of potential organ donors. Under section 1138(a)(1)(C) of the Act, every participating hospital must have an agreement to identify potential donors only with that particular designated OPO.

However, section 1138(a)(2) of the Act provides that a hospital may obtain a waiver of these requirements from the Secretary under certain specified conditions. A waiver allows the hospital to have an agreement with an OPO, other than the one initially designated by CMS, if the hospital meets certain conditions specified in section 1138(a)(2) of the Act. In addition, the Secretary may review additional criteria described in section 1138(a)(2)(B) of the Act to evaluate the hospital's request for a waiver.

Section 1138(a)(2)(A) of the Act states that in granting a waiver, the Secretary must determine that the waiver—(1) is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver. In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider, among other factors: (1) Cost-effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO due to the changes made in definitions for metropolitan statistical areas (MSAs); and (4) the length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO. Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver application within 30 days of receiving the application and offer interested parties an opportunity to comment in writing for 60 days, beginning on the publication date in the **Federal Register**.

The criteria that the Secretary uses to evaluate the waiver in these cases are the same as those described above under sections 1138(a)(2)(A) and (B) of the Act and have been incorporated into the regulations at § 486.316(e) and (f).

II. Waiver Request Procedures

In October 1995, we issued a Program Memorandum (Transmittal No. A–95–11) detailing the waiver process and discussing the information that hospitals must provide in requesting a waiver. We indicated that upon receipt of the waiver requests, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

According to these requirements, we will review the requests and comments received. During the review process, we may consult on an as-needed basis with the Public Health Service's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a final determination on the waiver requests and notify the affected hospitals and OPOs.

III. Hospital Waiver Requests

As permitted by § 486.316(e), three hospitals have requested waivers in order to enter into agreements with alternative, out-of-area OPOs. The listing below indicates the name of the facility, the city and State of the facility, the requested OPO, and the currently designated area OPO. This request is not a result of a governmental change; therefore, the exception under § 486.316(g) does not apply to these three hospitals. These hospitals must continue to work with their designated OPOs until the completion of our review.

Name of facility	City	State	Requested OPO	Designated OPO
Portage Health System	Hancock	MI	MIOP	WIWU
Trace Regional Hospital	Houston	MS	MSOP	TNMS
SCCI Hospital	Lima	OH	OHLP	OHLC

IV. Keys to the OPO Codes

The keys to the acronyms used in the listings to identify OPOs and their addresses are as follows:

MIOP
ORGAN PROCUREMENT AGENCY OF MICHIGAN
2203 Platt Road
Ann Arbor, Michigan 48104

MSOP
MISSISSIPPI ORGAN RECOVERY AGENCY, INC.
12 River Bend Place
Suite B
Jackson, Mississippi 39208

TNMS
MID-SOUTH TRANSPLANT FOUNDATION
910 Madison Avenue
Suite 1002
Memphis, Tennessee 38103

WIWU
UNIVERSITY OF WISCONSIN OPO
University of Wisconsin Hospitals and Clinics
600 Highland Avenue
Madison, Wisconsin 53792

OHLP
LIFELINE OF OHIO
770 Kinnear Road
Suite 200
Columbus, Ohio 43212

OHLC
LIFE CONNECTION OF OHIO
40 Wyoming Street
Dayton, Ohio 45409

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques or other forms of information technology.

Section 486.316 sets forth the requirements for a Medicare or Medicaid participating hospital to request a waiver permitting the hospital to have an agreement with an OPO other than the OPO designated for the service area in which the hospital is located. The burden associated with these requirements is currently approved under OMB 0938–0688, HCFA–R–13, Conditions of Coverage for Organ

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