Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12516. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for an enzyme immunoassay to be used as an aid in the diagnosis of patients with transitional cell carcinoma of the urinary tract.

Procedure: On December 13, 1999, from 10 a.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 1, 1999. On December 13, 1999, oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:15 a.m. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 1, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On December 13, 1999, from 9:30 a.m. to 10 a.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future device submissions (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to permit discussion of this information.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 17, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–30704 Filed 11–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Radiological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Radiological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 16, 1999, 8:30 a.m. to 5 p.m.

Location: DoubleTree Hotel, Plaza Ballroom, 1750 Rockville Pike, Rockville, MD.

Contact Person: Robert J. Doyle, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd. Rockville, MD 20850, 301–594–1212, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12526. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a digital mammography device.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 8, 1999. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m. Near the end of the committee deliberations, a 30 minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 8, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 15, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–30705 Filed 11–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4577]

Draft ''Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing a draft guidance document entitled ''Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma.'' The purpose of the draft guidance document is to seek public comment on FDA's approach to regulating nucleic acid testing for infectious agents when intended for use in blood donor screening and/or manufacturing of blood products. FDA is issuing the draft guidance document in response to requests from manufacturers for guidance in the development of nucleic acid testing of plasma pools for infectious agents.

DATES: Written comments may be submitted at any time, however, comments should be submitted by January 25, 2000, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma'' 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 that office in processing your requests. The draft guidance 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 draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, 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 guidance document entitled ''Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma.'' The draft guidance document outlines FDA's approach to the development and implementation of nucleic acid testing of infectious agents when intended to screen blood donors for manufacturing of blood products. FDA considers nucleic acid testing of plasma pools to be donor screening.

The draft guidance document represents the agency's current thinking regarding nucleic acid testing of pooled plasma for viral detection in blood and blood products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

II. Comments

The draft guidance document is being distributed for comment purposes only. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by January 25, 2000, to ensure their adequate consideration in preparation of the final document. 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. A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at http://www.fda.gov/cber/guidelines.htm.

Dated: November 15, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy,

[FR Doc. 99–30702 Filed 11–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Docket Identifier: HCFA–R–0250]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of 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: Skilled Nursing Facility (SNF) Resident Assessment MDS Data and Supporting Regulations in 42 CFR 413.343 and 424.32; *Form No.:* HCFA–R–250 (OMB# 0938–0739); *Use:* Skilled Nursing Facilities (SNFs) are required to submit Resident Assessment Data as described at 42 CFR 483.20 in the manner necessary to administer the payment rate methodology described in 42 CFR 413.337. Pursuant to sections 4204(b) and 4214(d) of OBRA 1987, the current requirements related to the submission and retention of resident assessment data for the 5th, 30th and 60th days following admission, necessary to administer the payment rate methodology described in 413.337, is subject to the Paperwork Reduction Act; *Emergency:* Monthly; *Affected Public:* Business or other for-profit, and Not-for-profit; *Number of Respondents:* 17,000; *Total Annual Responses:* 204,000; *Total Annual Hours:* 5,696,218.25.

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, Security and Standards Group, Division of HCFA Enterprise Standards Attention: Julie Brown, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: November 16, 1999.

John Parmigiani,

Acting HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–30786 Filed 11–24–99; 8:45 am]

BILLING CODE 4120–03–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: ''Immunoconjugates Having High Binding Affinity''

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This notice in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(I) that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive world-wide license to U.S. Patent Applications 09/321,490, entitled: ''Immunoconjugates Having High Binding Affinity'' and corresponding foreign patent applications to NeoPharm, Inc. having a place of business in Bannockburn, Illinois. The patent rights in these inventions have been assigned to the United States of America and the