Office received a patent term restoration application for Baycol (U.S. Patent No. 5,006,530) from Bayer Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 9, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Baycol represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Baycol is 2,262 days. Of this time, 1,896 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective: April 19, 1991. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 19, 1991.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the act: June 26, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Baycol (NDA 20–740) was initially submitted on June 26, 1996.

3. The date the application was approved: June 26, 1997. FDA has verified the applicant's claim that NDA 20–740 was approved on June 26, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 890 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written comments and ask for a redetermination by July 10, 2001. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 7, 2001. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information 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. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 2001.

Jane A. Axelrad,

Associate Director for Policy, Canter for Drug Evaluation and Research.

[FR Doc. 01–11961 Filed 5–10–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0177]

Draft Guidance for Industry on Immunotoxicology Evaluation of Investigational New Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Immunotoxicology Evaluation of Investigational New Drugs.'' This draft guidance provides recommendations for sponsors of investigational new drugs (INDs) on the parameters that should be routinely assessed in toxicology studies to determine effects on immune function, when additional specific immunotoxicity studies should be conducted, and when additional mechanistic information could better evaluate a given effect on the immune system.

DATES: Submit written comments on the draft guidance by August 9, 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 Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD–24), Food and Drug Administration, 5600 Fishers Lane,Rockville, MD 20857, 301–594–5476.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Immunotoxicology Evaluation of Investigational New Drugs.'' The immune system consists of a diffuse and complex set of cells and organs that have complicated interactions with each other and with other physiological systems. These complexities make the detection and evaluation of drug-induced immunotoxicity in animal models difficult. Immunotoxicologic findings could suggest the need for additional followup studies, particularly if the observed adverse effects are serious. The objective of these followup studies would be to investigate the nature and mechanism of the immunotoxic effects. Immunotoxicity findings could lead to modifications in proposed clinical trials or could be included in the investigator's brochure or product label. Rarely, immunotoxicity findings could indicate that a drug is unsafe for some types of clinical investigations or certain indications.

For the safety assessment of INDs, specific immunotoxicity testing should be conducted when drugs are to be administered by inhalation or topically. Specific immunotoxicity studies should also be considered for safety assessment purposes when: (1) The drug has the potential to elicit an anti-drug immune response; (2) use of the drug during pregnancy is likely; (3) there is an absence of immunotoxicity findings in the toxicology studies, but there is significant accumulation or retention of the drug in immune system tissues; or (4) the drug will be used to treat an immune-deficiency disease such as the human immunodeficiency virus (HIV). In most other instances, specific immunotoxicity studies are generally not needed to support initial clinical trials or continued development.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The

draft guidance represents the agency's current thinking on immunotoxicology evaluation of INDs. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. 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. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: May 4, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–11879 Filed 5–10–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10040]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, Health and Human Services.

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: New collection; *Title of Information Collection:* NMEP Regional Survey of Medicare Beneficiaries; *Form No.:* HCFA–10040 (OMB# 0938–NEW); *Use:* HCFA is proposing to conduct a survey by selecting 2,000 Medicare beneficiaries per HCFA region from HCFA's administrative databases with oversampling for underserved populations as a part of the continuous assessment on the knowledge and understanding of the Medicare program and the NMEP/Medicare+Choice outreach and educational efforts to systematically quantify current knowledge and awareness and to assess future direction; *Frequency:* On occasion; *Affected Public:* Individuals or households, Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 20,000; *Total Annual Responses:* 20,000; *Total Annual Hours:* 5,000.

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: May 2, 2001.

John P. Burke III,

Reports Clearance Officer, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–11869 Filed 5–10–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

HRSA AIDS Advisory Committee; Notice of Meeting; Correction

In **Federal Register** Document 01–10229 appearing on page 20820 in the issue for Wednesday, April 25, 2001, the location of the meeting scheduled on June 4, 2001, from 8:30 a.m.–5 p.m. has changed. This meeting will be held at: Holiday Inn Select (Conference Plaza),130 Claremont Avenue,Decatur, Georgia 30030,Telephone: 800–225–6079.

Dated: May 7, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–11880 Filed 5–10–01; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4650–N–34]

Notice of Submission of Proposed Information Collection to OMB; Annual Lead-Based Paint Activity Report

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* June 11, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2577–0090) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents