(2) (10 points) The extent to which the applicant has shown that partnerships have been ongoing and viable and have included copies of the following: (1) Agendas for all partnership meetings for calendar years 1999 and 2000; and (2) the executive summary and table of contents from the State Plan for Arthritis.

c. Surveillance (15 Points)

The extent to which the applicant describes the status of existing state-based arthritis surveillance. The extent to which the applicant describes future surveillance plans including data to be collected, the rationale for its selection and its programmatic application.

d. Interventions (25 Points)

The extent to which the applicant describes the proposed intervention(s) activity, the rationale for selection, the target population, the appropriateness of the intervention for the target population, and the implementation and evaluation strategies.

3. Budget (Not Scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with stated objectives and planned program activities.

**H. Other Requirements**

*Technical Reporting Requirements*

Provide CDC with original plus two copies of:

1. Semi-annual progress reports.
2. Financial status report, no more than 90 days after the end of the budget period;
3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment III in the application kit.

AR–7 Executive Order 12372 Review
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions

**I. Authority and Catalog of Federal Domestic Assistance Number**

This program is authorized under section 301(a) and 317 of the Public Health Service Act, [42 U.S.C. section 241(a) and 247(b)], as amended. The Catalog of Federal Domestic Assistance number is 93.945.

**J. Where To Obtain Additional Information**

This and other CDC announcements can be found on the CDC home page Internet address—http://www.cdc.gov Click on ''Funding'' then ''Grants and Cooperative Agreements''. Should you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Michelle Copeland, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Program Announcement 01097, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number: (770) 488–2686,E-mail address: stc8@cdc.gov

For program technical assistance, contact: Sakeena Smith, MPH, Senior Project Officer, Arthritis Program, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, Mailstop K–45, Atlanta, GA 30341, Telephone number: (770) 488–5440, E-mail address: SSmith1@cdc.gov

Dated: May 7, 2001.

**Henry S. Cassell III,**

*Acting Director, Procurement and Grants Office,Centers for Disease Control and Prevention (CDC).*

[FR Doc. 01–11896 Filed 5–10–01; 8:45 am]

**BILLING CODE 4163–18–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### [Docket No. 97E–0465]

### Determination of Regulatory Review Period for Purposes of Patent Extension; Baycol

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for Baycol and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

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

**FOR FURTHER INFORMATION CONTACT:** Claudia Grillo, Regulatory Policy Staff (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued) FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Baycol (cerivastatin sodium). Baycol is indicated as an adjunct to diet for the reduction of elevated total and LDL cholesterol levels in patients with primary hypercholesterolemia and mixed dyslipidemia (Frederickson Types IIa and IIb) when the response to dietary restriction of saturated fat and cholesterol and other nonpharmacological measures alone has been inadequate. Subsequent to this approval, the Patent and Trademark

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