Dated: November 19, 2004.

**Alvin Hall,**

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

[FR Doc. 04–26319 Filed 11–26–04; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 1997N–0484S]**

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 25, 2004 (69 FR 29786), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0543. The approval expires on May 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: November 19, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–26235 Filed 11–26–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004N–0204]**

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 19, 2004 (69 FR 51468), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0233. The approval expires on November 30, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: November 19, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–26270 Filed 11–26–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004P–0141]**

### Determination That 7.5% and 8.4% Sodium Bicarbonate Injection in Polyethylene Terephthalate Abboject Vials Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that 7.5% and 8.4% sodium bicarbonate injection in polyethylene terephthalate (PET) Abboject vials were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for 7.5% and 8.4% sodium bicarbonate injection.

**FOR FURTHER INFORMATION CONTACT:** Nicole Mueller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an abbreviated new drug application (ANDA) procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the

agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162) (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

The drug products 7.5% and 8.4% sodium bicarbonate injection in PET Abbject vials are the subject of approved NDA 19–443 held by Abbott Laboratories. The drug products 7.5% and 8.4% sodium bicarbonate injection in PET Abbject vials are indicated for the treatment of metabolic acidosis, certain drug overdosage, and severe diarrhea. The holder of the application for 7.5% and 8.4% sodium bicarbonate injection in PET Abbject vials requested a voluntary withdrawal and the marketing of the drug products was discontinued (61 FR 40649, August 5, 1996). In a citizen petition dated March 18, 2004 (Docket No. 2004P–0141), submitted under 21 CFR 10.30 and 314.122, Abbott Laboratories requested that the agency determine whether 7.5% and 8.4% sodium bicarbonate injection in PET Abbject vials were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Abbott Laboratories' 7.5% and 8.4% sodium bicarbonate injection in PET Abbject vials were not withdrawn from sale for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse event reports and has found no information that would indicate that these products were withdrawn for reasons of safety or effectiveness.

For the reasons outlined, FDA determines that Abbott Laboratories' 7.5% and 8.4% sodium bicarbonate injection in PET Abbject vials were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list 7.5% and 8.4% sodium bicarbonate injection in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to 7.5% and 8.4% sodium bicarbonate injection may be approved by the agency.

Dated: November 18, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–26271 Filed 11–26–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004D–0484]**

### Draft Guidance for Industry on the Role of Human Immunodeficiency Virus Drug Resistance Testing in Antiretroviral Drug Development; 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 ''Role of HIV Drug Resistance Testing in Antiretroviral Drug Development.'' This draft guidance is intended to assist sponsors in the clinical development of drugs for the treatment of human immunodeficiency virus (HIV) infection. Specifically, the draft guidance addresses the role of HIV resistance testing during antiretroviral drug development and postmarketing. The draft guidance is also intended to serve as a focus for continued discussions among the Division of Antiviral Drug Product (DAVDP) in FDA's Center for Drug Evaluation and Research, pharmaceutical sponsors, the academic community, and the public.

**DATES:** Submit written or electronic comments on the draft guidance by February 28, 2005. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of this draft guidance to the Division of Drug Information (HFD–240), 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 Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey S. Murray, or Kimberly A. Struble Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2330.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Role of HIV Drug Resistance Testing in Antiretroviral Drug Development.'' This draft guidance addresses the role of HIV resistance testing during antiretroviral drug development and postmarketing. The draft guidance is based on the following: (1) A 2-day session of the Antiviral Drug Product advisory committee convened November 2 and 3, 1999, to address issues relating to HIV resistance testing; (2) the DAVDP's experience with reviewing resistance data for antiretroviral drugs; and (3) input from pharmaceutical sponsors and the HIV community.

The draft guidance discusses the nonclinical studies (mechanism of action; antiviral activity in vitro; cytotoxicity/therapeutic index; and the effects of serum protein binding on antiviral activity) we recommend be completed prior to the initiation of phase 1 clinical studies in HIV-infected patients. In addition, the draft guidance addresses the use of resistance testing in the clinical phases of drug development and recommends the type of information that should be collected and the types of analyses that should be conducted to characterize an antiretroviral's resistance profile. The draft guidance also reviews the role of resistance testing in initial activity and dose-finding, for study enrollment criteria, for background regimen selection, and to establish an indication. Included in this draft guidance are two appendices: (1) A template for submitting HIV resistance data and (2) information on the genetic threshold for resistance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on the role of HIV resistance testing in antiretroviral drug development. 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.