approval, the Patent and Trademark Office received a patent term restoration application for MACUGEN (U.S. Patent No. 6,051,698) from Gilead Sciences, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 28, 2005, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of MACUGEN represented the first permitted commercial marketing or use of the product. 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 MACUGEN is 2,312 days. Of this time, 2,128 days occurred during the testing phase of the regulatory review period, while 184 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: August 21, 1998. The applicant claims August 20, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 21, 1998, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: June 17, 2004. The applicant claims March 17, 2004, as the date the new drug application (NDA) for MACUGEN (NDA 21–756) was initially submitted. The applicant claims this is the date it submitted the first module of NDA 21–756, which was submitted in several modules as part of a rolling NDA submission procedure. It is FDA's position that the approval phase begins when the marketing application is complete. A review of FDA records reveals that the final module of the marketing application was submitted on June 17, 2004, which is considered to be the NDA initially submitted date.

3. *The date the application was approved*: December 17, 2004. FDA has verified the applicant's claim that NDA 21–756 was approved on December 17, 2004.

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 990 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by November 20, 2006. 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 March 19, 2007. 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 Division of Dockets Management. Three copies of any mailed 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 1, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–15556 Filed 9–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0303]

Draft Guidance for Industry on Public Availability of Labeling Changes in ''Changes Being Effected'' Supplements; 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 ''Public Availability of Labeling Changes in 'Changes Being Effected' Supplements.'' The guidance announces to holders of a new drug application (NDA), an abbreviated new drug application (ANDA), or a biologics license application (BLA), who intend to submit a ''Changes Being Effected'' supplement (CBE supplement) to make a postapproval labeling change, that FDA will make labeling revisions identified in a CBE supplement publicly available upon receipt of the supplement by FDA. The guidance does not have any bearing on supplements that relate to chemistry, manufacturing, and controls changes, nor does it expand the circumstances in which an ANDA holder may effect labeling changes via a CBE supplement.

DATES: Submit written or electronic comments on the draft guidance by November 20, 2006. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the 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: Meredith S. Francis, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Public Availability of Labeling Changes in 'Changes Being Effected' Supplements.'' FDA has begun an initiative to facilitate computerized access to drug information by consumers, pharmacists, and health care providers so that they will have faster and more comprehensive access to drug information. As part of this initiative, the agency has been involved in the development of a computerized repository of a broad array of drug information, known as ''DailyMed.'' Among other things, DailyMed contains the information referred to as ''content of labeling,'' which includes all the information found in prescription drug labeling and over-the-counter (OTC) drug facts labeling, including all text, tables, and figures (see 21 CFR 314.50(l)(1)(i)). To maximize its ability to serve as a useful resource to consumers, pharmacists, and health care providers, DailyMed must contain the

most up-to-date and comprehensive drug information available.

Sections 314.70 and 601.12 (21 CFR 314.70 and 601.12) of FDA regulations identify the types of supplemental applications that must be submitted to FDA to effect a labeling change to approved NDAs, ANDAs, and BLAs. Certain types of changes to labeling should receive FDA approval before the changes are implemented. These include all labeling changes that do not fall under § 314.70(c)(6)(iii), (d)(2)(ix), or (d)(2)(x), or under § 601.12(f)(2) or (f)(3). Other changes may be implemented by a sponsor upon the agency's receipt of a CBE supplement. These changes are identified in §§ 314.70(c)(6)(iii) and 601.12(f)(2)(i).

In the past, FDA has not made labeling publicly available until it has been approved, either under a pre-approval supplement or under a CBE supplement. To make the most current labeling submitted to FDA available to health care practitioners and the public, and to facilitate the DailyMed initiative, FDA will make the revised labeling proposed in a CBE supplement publicly available on its Web site and through DailyMed shortly after the CBE supplement is received and before FDA has necessarily reviewed or approved it. If, after reviewing the CBE supplement, FDA decides it should not be approved, FDA will either: (1) Remove the labeling submitted with the CBE supplement from FDA's Web site and from DailyMed and replace that labeling with the previous labeling; or (2) recommend the sponsor amend its labeling and, after the sponsor submits the amended labeling, post the amended labeling on FDA's Web site and provide it to DailyMed promptly.

A sponsor should not submit a CBE supplement to FDA until the sponsor is ready to distribute the labeling that it proposes in that CBE supplement. FDA will consider the submission of a CBE supplement to be consent by the sponsor to post the proposed labeling on FDA's Web site and on DailyMed.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on public availability of labeling changes in CBE supplements. 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 may be seen in the Division of Dockets Management 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: September 13, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–7983 Filed 9–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2384–06; DHS Docket No. USCIS–2006–0048]

RIN 1615–ZA39

Termination of the Designation of Liberia for Temporary Protected Status; Automatic Extension of Employment Authorization Documentation for Liberia TPS Beneficiaries

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Notice of termination of temporary protected status for Liberia.

SUMMARY: Following a review of country conditions and consultations with the appropriate Government agencies, the Secretary of the Department of Homeland Security (DHS) has determined that the temporary protected status (TPS) designation of Liberia should be terminated. This termination will not take effect until October 1, 2007, to provide for an orderly transition. This Notice informs the public of the termination of the Liberia TPS designation and sets forth procedures for nationals of Liberia (or aliens having no nationality who last habitually resided in Liberia) with TPS to re-register for TPS benefits. Re-registration is limited to persons who have previously registered for TPS under the designation of Liberia and whose application was granted or remains pending. Liberians (or aliens having no nationality who last habitually resided in Liberia) who have not previously been granted TPS, or who do not already have a pending application for TPS under the designation for Liberia, may not file under late initial filing provisions. Late initial filings (LIFs) are only allowed during an extension of a designation of TPS.

Given the timeframes involved with processing TPS re-registrants, DHS recognizes that re-registrants might not receive a new EAD until after their current EAD expires on October 1, 2006. Accordingly, this Notice automatically extends the validity of EADs issued under the designation of TPS for Liberia for six months through April 1, 2007, and explains how TPS beneficiaries and their employers may determine which EADs are automatically extended. New EADs with an expiration date of September 30, 2007, will be issued to eligible TPS beneficiaries who timely re-register and apply for an EAD.

DATES: *Effective Dates:* The termination of Liberia's TPS designation is effective 12:01 a.m., local time, October 1, 2007. To maintain TPS benefits through the 12 months leading up to the effective date of the termination, Liberian TPS beneficiaries must comply with the re-registration requirements described in this Notice. The 60-day re-registration period begins September 20, 2006 and ends November 20, 2006.

FOR FURTHER INFORMATION CONTACT: Matthew Horner, Status and Family Branch, Service Center Operations, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue, NW., 2nd Floor, Washington, DC 20529, telephone (202) 272–1505. This is not a toll free number.

SUPPLEMENTARY INFORMATION:

Abbreviations and Terms Used in This Document

Act—Immigration and Nationality Act
ASC—USCIS Application Support Center
DHS—Department of Homeland Security
DOS—Department of State
EAD—Employment Authorization Document
Secretary—Secretary of Homeland Security
TPS—Temporary Protected Status
USCIS—U.S. Citizenship and Immigration Services