[FR Doc. 2011–30450 Filed 11–25–11; 8:45 am]
BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–P–0488]

Determination That TAXOTERE (Docetaxel) Injection, 40 Milligrams/Milliliter Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Drug Administration (FDA) has determined that TAXOTERE (docetaxel) Injection, 40 milligrams/milliliter (mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for docetaxel injection, 40 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nam Kim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6320, Silver Spring, MD 20993–0002, (301) 796–3472.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants 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. ANDA applicants 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 known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed 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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

TAXOTERE (docetaxel) Injection, 40 mg/mL is the subject of NDA 20–449, held by Sanofi-aventis U.S., and initially approved on May 14, 1996. TAXOTERE is indicated for breast cancer, non-small cell lung cancer, hormone refractory prostate cancer, gastric adenocarcinoma, and squamous cell carcinoma of the head and neck cancer as described in detail on the drug product's labeling.

TAXOTERE (docetaxel) Injection, 40 mg/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Sandoz, Inc. (Sandoz), submitted a citizen petition dated June 21, 2011 (Docket No. FDA–2011–P–0488), under 21 CFR 10.30, requesting that the Agency determine whether TAXOTERE (docetaxel) Injection, 40 mg/mL, was withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that TAXOTERE (docetaxel) Injection, 40 mg/mL was not withdrawn for reasons of safety or effectiveness. The petitioner Sandoz has identified no data or other information suggesting that TAXOTERE (docetaxel) Injection, 40 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of TAXOTERE (docetaxel) Injection, 40 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list TAXOTERE (docetaxel) Injection, 40 mg/mL, 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 TAXOTERE (docetaxel) Injection, 40 mg/mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–30472 Filed 11–25–11; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0799]

Draft Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples From Donors of Whole Blood and Blood Components, Including Source Plasma, to Reduce the Risk of Transmission of Hepatitis B Virus

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Use of Nucleic Acid Tests (NAT) on Pooled and Individual Samples from Donors of Whole Blood and Blood Components (including Recovered Plasma, Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of Hepatitis B Virus (HBV), and Requalification of Donors Who Test HBV NAT Positive,'' dated November 2011. The draft guidance document provides recommendations on the use of FDA-licensed nucleic acid tests (NAT) to screen blood donors for hepatitis B virus (HBV) deoxyribonucleic acid (DNA) and recommendations for product testing and disposition, donor management, methods for donor requalification, and product labeling. In addition, the draft guidance provides notification that FDA considers the use of an FDA-licensed HBV NAT to be necessary to reduce adequately and appropriately the risk of transmission of HBV. The guidance is intended for blood establishments that

collect Whole Blood and blood components for transfusion or for further manufacture, including recovered plasma, Source Plasma and Source Leukocytes. The draft guidance, when finalized, is intended to supplement previous memoranda and guidance from FDA concerning the testing of donations for hepatitis B surface antigen (HBsAg) and antibody to hepatitis B core antigen (anti-HBc), and the management of donors and units mentioned in those documents.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 27, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–(800) 835–4709 or (301) 827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul Levine, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, (301) 827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Use of Nucleic Acid Tests (NAT) on Pooled and Individual Samples from Donors of Whole Blood and Blood Components (including Recovered Plasma, Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of Hepatitis B Virus (HBV), and Requalification of Donors Who Test HBV NAT Positive,'' dated November 2011. FDA is providing blood establishments that collect Whole Blood and blood components for transfusion or for further manufacture, including recovered plasma, Source Plasma and Source Leukocytes; with recommendations concerning the use of FDA-licensed NAT to screen blood donors for HBV DNA. FDA is also providing these blood establishments with recommendations for product testing and disposition, donor management, methods for donor requalification, and product labeling.

In addition, FDA is notifying those blood establishments that FDA considers the use of an FDA-licensed HBV NAT to be necessary to reduce adequately and appropriately the risk of transmission of HBV. FDA-licensed HBV NAT can detect evidence of infection at an earlier stage than is possible using previously approved HBsAg and anti-HBc tests. Therefore, FDA is recommending the use of an FDA-licensed HBV NAT, in accordance with the requirements under 610.40(a) and (b) (21 CFR 610.40(a) and (b)).

The draft guidance, when finalized, is intended to supplement previous memoranda and guidance from FDA to blood establishments concerning the testing of donations for HBsAg and anti-HBc, and the management of donors and units mentioned in those documents. Note that testing Whole Blood and blood components for transfusion and Source Leukocytes for further manufacture for HBsAg and anti-HBc, and Source Plasma for HBsAg should continue when a blood establishment implements HBV NAT. FDA may consider advancements in technology for testing blood donations, as well as data obtained following the implementation of HBV NAT, to make future recommendations on adequate and appropriate testing for HBV.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 606.121, 610.40 and 640.70 have been approved under OMB Control Numbers 0910–0537, 0910–0116, and 0910–0338, respectively.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: November 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–30449 Filed 11–25–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0386]

Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses.'' This guidance document provides industry and Agency staff with recommendations for studies to establish the performance characteristics of in vitro diagnostic devices (IVDs) intended for the