Application No.	Drug	Applicant	Initial approval date
Do.	DURANEST (epinephrine bitartrate; etidocaine hydrochloride) Injection 1.5%.	.....do	Do.
Do.	DURANEST (epinephrine; etidocaine hydrochloride) Injection 0.5%	.....do	Do.
Do.	DURANEST (etidocaine hydrochloride) Injection 0.5%	.....do	Do.
Do.	DURANEST (etidocaine hydrochloride) Injection 1%	.....do	Do.
NDA 21–384	DURANEST (epinephrine bitartrate; etidocaine hydrochloride) Injection 1.5%.	DENTSPLY Pharmaceutical	Do.

The drug products listed in the table in this document are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Lachman Consultant Services, Inc. submitted a citizen petition dated September 25, 2008 (Docket No. FDA–2008–P–0527), under 21 CFR 10.30, requesting that the Agency determine whether DURANEST (etidocaine hydrochloride) Injection, 0.5% and 1%, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not request a determination for the other DURANEST drug products listed in the table in this document, those drug products have also been discontinued. On our own initiative, we have also determined whether those products were withdrawn for safety or effectiveness reasons.

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time, FDA has determined under § 314.161 that the DURANEST drug products listed in the table in this document were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that the DURANEST drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of the DURANEST drug products from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that the products were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the DURANEST drug products listed 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 any of the DURANEST drug products listed in the table in this document 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 these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 8, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–6039 Filed 3–12–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0022]

Draft Guidance for Industry on Direct-to-Consumer Television Advertisements—the Food and Drug Administration Amendments Act of 2007 Direct-to-Consumer Television Ad Pre-Dissemination Review Program; 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 ''Direct-to-Consumer Television Advertisements—FDAAA DTC Television Ad Pre-Dissemination Review Program.'' This draft guidance is intended to assist sponsors of human prescription drug products, including biological drug products, who are subject to the pre-dissemination review of television advertisements (TV ads) provision of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). (The term ''pre-dissemination review'' is used throughout the guidance to refer to review under the FD&C Act, which is entitled ''Prereview of Television Advertisements.'') The draft guidance describes which TV ads FDA intends to make subject to this provision, explains how FDA will notify sponsors that an ad is subject to review under this provision, and describes the general and center-specific procedures sponsors should follow to submit their TV ads to FDA for pre-dissemination review in compliance with the FD&C Act. These proposed TV ads will be subject to a 45-calendar day review clock by FDA.

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 comments 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 May 14, 2012. Submit written comments on the proposed collection of information by May 14, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or 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 that office in processing your requests. The 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: Regarding human prescription drugs: Marci Kiester, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3368, Silver Spring, MD 20993–0002, 301–796–1200.

Regarding prescription human biological products: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike,

suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Direct-to-Consumer Television Advertisements—FDAAA DTC Television Ad Pre-Dissemination Review Program.'' The Food and Drug Administration Amendments Act of 2007 (FDAAA) added new section 503B to the FD&C Act, which gives FDA the authority to ''* * * require the submission of any television advertisement for a drug * * * not later than 45 days before dissemination of the television advertisement.'' In conducting a review of a TV ad under this section, FDA may make recommendations with respect to information included in the label of the drug on:

- Changes that are necessary to protect the consumer good and well-being, or that are consistent with prescribing information for the product under review; and
- Statements for inclusion in the advertisement to address the specific efficacy of the drug as it relates to specific population groups, including elderly populations, children, and racial and ethnic minorities, if appropriate and if such information exists. (21 U.S.C. 353b(b)(1) and (b)(2)).

FDA is issuing this guidance to communicate the categories of TV ads it generally intends to require sponsors to submit under this provision, to explain how it will notify sponsors that FDA is requiring review under section 503B of the FD&C Act for ads for a particular drug or group of drugs, and to provide sponsors with recommendations for the information they need to properly submit these ads to the Agency for pre-dissemination review.

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 which TV ads it intends to require be submitted under section 503B of the FD&C Act and on the submission process for these ads. 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. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c), and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

FDA estimates the burden of this collection of information as follows:

Based on the number of TV ads produced annually by sponsors of human prescription drug and biological products, we estimate that we will receive approximately 80 ads per year for pre-dissemination review from approximately 30 sponsors for the Center for Drug Evaluation and Research (CDER) and 2 ads from 2 sponsors for CBER. FDA professionals familiar with TV ads and the recommendations in the draft guidance estimate that it should take a sponsor approximately 25 hours to prepare and send the pre-dissemination review package and documentation. This burden estimate includes all of the information specified for CDER and CBER in the draft guidance section entitled ''Contents of a Complete Pre-Dissemination Review Package'' and in the Appendix entitled ''Center-Specific Submission Procedures.''

FDA cannot provide final comments on the acceptability of a TV ad without reviewing a final recorded version in its entirety. However, some sponsors may wish to receive comments from the Agency before producing a final recorded version. Once the final recorded version is produced, it should be submitted to the Agency for pre-dissemination review. In this document, we have included in the table 1 burden estimate for section 503B of the FD&C Act the time necessary to prepare the final ad for submission.

If FDA receives an incomplete submission package from a sponsor, we will inform that sponsor and request a submission package that contains the missing materials. We estimate that we will request a package containing missing materials a total of 6 times from 6 different sponsors annually, and that it will take each sponsor 5 hours to prepare the resubmission with the missing materials. This resubmission with missing materials is included in table 1 of this document.

There is a 45-day review clock for TV ads submitted under section 503B. Under this review clock, FDA must notify the sponsor if the Agency is not able to provide comments within a 45-day timeframe. When a sponsor is notified by FDA that the Agency is not able to provide comments, the sponsor should inform FDA whether it will disseminate the TV ad without waiting for FDA comments, or wait for the Agency's comments before disseminating the ad. We anticipate that we will be able to review and comment on all TV ads submitted to the Agency within the 45-day review clock timeframe, but for the purposes of this collection of information, we are estimating that the Agency will be unable to provide comments within the 45-day timeframe to one sponsor for one TV ad per year. We estimate that the time needed for a sponsor to prepare a letter informing FDA of its decision to disseminate or not to disseminate the TV ad will be 1 hour.

This draft guidance also refers to previously approved collections of information found in FDA regulations. In the draft guidance, the Agency has noted that sponsors subject to the section 503B pre-dissemination review provision may revise their TV ads after receiving comments from the Agency but before disseminating the ads, and may wish to request additional comments under the voluntary submission process delineated in § 202.1(j)(4) (21 CFR 202.1(j)(4)). The collections of information in § 202.1(j)(4) have been approved under OMB control number 0910–0686. For pre-dissemination review packages for biological drug products under the purview of CBER, the Agency is requesting a copy of the most current version of Form FDA 2253 to

accompany the TV ad submission package. This collection of information for Form FDA 2253 has been approved under OMB control number 0910–0001.

Therefore, we estimate the annual reporting burden as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of submission	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Advertisements prepared in accordance with section 503B of the FD&C Act	32	2.56	82	25	2,050
Resubmissions of incomplete submission packages	6	1	6	5	30
45-Day review clock decision letter	1	1	1	1	1
Total					2,581

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Comments

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. 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 document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: March 8, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–6040 Filed 3–12–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Public Workshop on Minimal Residual Disease; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop to provide a forum for discussion of the use of minimal residual disease (MRD) as a biomarker for evaluating new drugs for the treatment of acute lymphoblastic leukemia (ALL). The meeting is cosponsored with the American Society of Clinical Oncology and will be the first in a series of workshops intended to bring together scientific and advocacy communities and the pharmaceutical and in vitro diagnostic device industries to help develop processes and procedures to qualify MRD as a biomarker of efficacy and/or response to treatment in a group of hematological malignancies.

DATES: *Date and Time:* The public workshop will be held on April 18, 2012, from 8 a.m. to 4 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave. Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002.

Contact Person: Christine Lincoln, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 22, rm. 6413, Silver Spring, MD 20993–0002, 301–796–2340.

SUPPLEMENTARY INFORMATION:

I. Background

Clinical data from patients with certain subtypes of acute and chronic leukemia suggest that MRD can be established as a surrogate endpoint for clinical trials and drug approval. This public workshop will provide a forum for discussion among scientific and advocacy communities and the pharmaceutical and in vitro diagnostic device industries of issues related to the qualification (validation) of MRD as a biomarker (i.e., a measurable characteristic that is predictive of disease outcome) that can be used to determine efficacy and/or response in evaluation of new drugs for the treatment of ALL. Although the data related to the prognostic significance of MRD are most extensive in the pediatric population, and are currently used to stratify patients for risk-adjusted therapy, MRD may also be pertinent to subtypes of adult ALL; hematologists who treat adult patients have been invited to participate, as well as hematologists who treat pediatric patients. Topics to be discussed at the workshop include: (1) Evaluation of the prognostic biomarker data that is currently available to support the qualification of MRD as a marker of response and/or efficacy in both pediatric and adult ALL; (2) the specificity, sensitivity, and comparability of techniques that might be used in a standardized fashion to measure MRD; (3) the performance characteristics and proficiency assessment of current technology platforms; and (4) the design and analysis of the clinical trials needed to establish the use of postinduction MRD as an alternative endpoint for approval of new drugs to treat ALL.

This workshop is part of a series in which FDA's Office of Hematology and Oncology Products will explore the utility of MRD as a surrogate endpoint in ALL (including ALL that has recurred), chronic lymphocytic leukemia (CLL), and acute myeloid leukemia (AML). Given the diverse etiologies, pathophysiologies, and natural histories of these diseases and current practice standards, separate consideration of MRD as a surrogate endpoint in each disease is warranted. FDA is seeking representation from both North American and European academic investigators as well as cooperative groups at the workshops. The workshops for CLL and AML are tentatively scheduled for October 10 and 11, 2012, respectively.

II. Attendance and Registration

FDA encourages patient advocates, representatives from industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Registration: There is no registration fee for the public workshop. To register electronically, please use the following Web site: *http://www.zoomerang.com/*