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/*

Survey/WEB22EJ4HRZLW9. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Seats are limited and conference space will be filled in the order in which registrations are received. Onsite registration will be available to the extent that space is available on the day of the conference.

Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Bldg. 1.

Dated: March 8, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–6038 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–0212]

Tobacco Product Analysis; Scientific Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), Center for Tobacco Products is announcing a scientific workshop to solicit feedback on analysis of tobacco products. The analyses of tobacco products often involve tobacco reference products, which are used primarily as controls to ensure that the results of the analyses are reliable and accurate. This scientific workshop will focus on understanding how tobacco reference products are used and the testing methods used to analyze tobacco products. FDA will invite speakers to address scientific and technical matters relating to the testing of tobacco reference products and the analytical methods used to measure constituent levels in tobacco products and smoke. FDA is also opening a public docket to receive comments on these topics.

DATES: *Dates and Time:* The public workshop will be held on April 11, 2012, from 8:30 a.m. to 5:30 p.m., and on April 12, 2012, from 8:30 a.m. to 4 p.m. Individuals who wish to attend the public workshop must register by close of business on March 30, 2012. Submit either electronic or written comments to the docket by May 11, 2012.

Location: The public workshop will be held at 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373.

Contact Person: Anuja Patel, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD, 20850, 1–877–287–1373, FAX: 240–276–3761, email: *workshop.CTPOS@fda.hhs.gov.*

Registration to Attend the Workshop and Requests for Oral Presentations: If you wish to attend the workshop or make an oral presentation at the workshop, please email your registration to *workshop.CTPOS@fda.hhs.gov* by close of business on March 30, 2012. Those without email access may register by contacting Anuja Patel (see *Contact Person*). Please provide contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the workshop will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing registration for the workshop at *http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm.*

There will be opportunities for audience participation at this workshop. FDA has included topics for comment in section II of this document. FDA will do its best to accommodate requests to speak during the workshop sessions, although questions from the audience may be limited. In addition, we strongly encourage submitting comments to the docket (see *Comments*).

If you need special accommodations because of disability, please contact Anuja Patel (see *Contact Person*) at least 7 days before the workshop.

Comments: Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments on any of the topics for discussion in section II of this document by May 11, 2012. Submit electronic comments 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. 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.

SUPPLEMENTARY INFORMATION:

I. Background and Workshop Topics

The purpose of this scientific workshop is to obtain information and comments from appropriate scientific experts on analysis of tobacco products. Such experts could include, but are not limited to, scientists from academia, tobacco product manufacturers, and contract testing laboratories. The workshop will include scientific experts who will present scientific and technical information on testing of tobacco reference products for different types of tobacco products. The types of tobacco reference products to be discussed include, but are not limited to, smoked tobacco products, smokeless tobacco products, and other tobacco products not classified as either smoked or smokeless products. FDA would like to discuss how the tobacco reference products are used for testing purposes to ensure accuracy of analysis of tobacco products. Tobacco reference products are analyzed alongside test tobacco products (i.e., during every step of the analysis). Tobacco reference products are intended for use during analysis of tobacco products and are not intended for human consumption. Tobacco reference products are finished tobacco products and are distinct from internal reference standards, which are chemicals or mixtures of chemicals. Internal reference standards are used during only certain steps of the analysis of test tobacco products (e.g., when running samples).

The scientific workshop will include discussion of analytical methods for measuring certain constituents in tobacco products and smoke. The aspects of analytical methods that will be discussed include extraction, separation, and detection methods. For example, FDA would like to get input from scientific experts on how tobacco-specific nitrosamines (TSNAs) are extracted from smokeless tobacco products and cigarette smoke particulate matter and what instrumentation (e.g., gas chromatography-mass spectrometry) is used to measure the levels of TSNAs.

FDA is interested in receiving substantive scientific input at the workshop and in the docket. The input from the scientific workshop may assist us in developing future scientific