

environmental strategies and interventions to improve the health of students and school staff by promoting healthy eating, physical activity, and a tobacco-free lifestyle; (2) supports implementation and evaluation of a coordinated approach to school health and best practices in health education; physical education and other physical activity programs; nutrition services; school health services; school counseling, psychological, and social services; health promotion for staff; family and community involvement; and school health and safety policies and environment; (3) provides leadership and consultation on how schools work and how to foster effective collaboration between the public health and education sectors; (4) documents and strengthens the scientific associations among chronic disease-related health risks, school-based health promotion initiatives, and academic achievement; (5) evaluates school-based policy, systems, and environmental changes and interventions to improve health behaviors and reduce chronic disease-related health risks among children and adolescents; (6) synthesizes and translates scientific research to develop and disseminate guidance, tools, and resources to help schools prevent chronic disease-related risks among children and adolescents; (7) supports efforts of national, state, and local surveillance systems to monitor chronic disease-related health risk behaviors among youth, along with the policies, programs, and practices schools implement to address those health risk behaviors; (8) strengthens efforts of national, state, and local programs to provide high quality professional development services to support school-based chronic disease prevention policies, programs, and practices; (9) in accomplishing the functions listed above, collaborates with other components of CDC and HHS; the U.S. Department of Education, U.S. Department of Agriculture, and other federal agencies; national professional, voluntary, and philanthropic organizations; international agencies; and other organizations as appropriate; and (10) assists other nations in reducing chronic disease-related health risks among children and adolescents and in implementing and improving school health programs.

Dated: January 20, 2012.

Sherri A. Berger,
Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2012-2531 Filed 2-3-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0672]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. **DATES:** Fax written comments on the collection of information by March 7, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: (202) 395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0577. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices (OMB Control Number 0910-0577)—Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C.

352), among other things, establishes requirements that the label or labeling of a medical device must meet so that it is not misbranded and subject to regulatory action. Section 301 of the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250) amended section 502 of the FD&C Act to add section 502(u) to require devices (both new and reprocessed) to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer. Thus, the name for this information collection activity has been changed to more accurately describe the information collection content.

Section 2(c) of the Medical Device User Fee Stabilization Act of 2005 (Pub. L. 109-43) amends section 502(u) of the FD&C Act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Under the amended provision, if the original SUD or an attachment to it prominently and conspicuously bears the name of the manufacturer, then the reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol, in a prominent and conspicuous manner on the device or attachment to the device. If the original SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse may identify itself using a detachable label that is intended to be affixed to the patient record.

The requirements of section 502(u) of the FD&C Act impose a minimal burden on industry. This section of the FD&C Act only requires the manufacturer, packer, or distributor of a device to include their name and address on the labeling of a device. This information is readily available to the establishment and easily supplied. From its registration and premarket submission database, FDA estimates that there are 10 establishments that distribute approximately 1,000 reprocessed SUDs. Each response is anticipated to take 0.1 hours resulting in a total burden to industry of 100 hours.

In the **Federal Register** of September 27, 2011 (76 FR 59704), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

FD&C Act section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
502(u)	10	100	1,000	.1	100

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

Dated: February 1, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–2555 Filed 2–3–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 21, 2012, from 8 a.m. to 12:45 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. 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 Building 1.

Contact Person: Caleb Briggs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, (301) 796–9001, Fax: (301) 847–8533, email: ODAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–(800) 741–8138 ((301) 443–0572 in the Washington, DC area), and follow the prompts to the desired center or product

area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 202497, MARQIBO (vincristine sulfate liposomes injection), application submitted by Talon Therapeutics, Inc. The proposed indication (use) for this product is for the treatment of adult patients with Philadelphia chromosome-negative acute lymphoblastic leukemia in second or greater relapse or whose disease has progressed following two or more treatment lines of anti-leukemia therapy.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 6, 2012. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time

requested to make their presentation on or before February 27, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 28, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caleb Briggs at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 31, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–2460 Filed 2–3–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0057]

Cardiovascular Metallic Implants: Corrosion, Surface Characterization, and Nickel Leaching; Public Workshop

AGENCY: Food and Drug Administration, HHS.