

hearing request filed by D.M. Graham Laboratories, Inc., was withdrawn on December 10, 2009. D.M. Graham Laboratories was previously acquired by Mallinckrodt, Inc., which is now part of Covidien, 172 Railroad Ave., Hobart, NY 13788. Teva Pharmaceuticals, the successor-in-interest to Sidmak Laboratories, withdrew its hearing request on February 15, 2010. Acura Pharmaceutical Co., 616 N. North Court, Palantine, IL 60067, successor to Halsey Drug Co., withdrew its hearing request on November 23, 2010.

FDA sent a letter to Merz Pharmaceuticals, LLC, P.O. Box 18806, Greensboro, NC 27419, successor to Mayrand, Inc., Pharmaceuticals, on November 16, 2010, requesting that this company withdraw or affirm its outstanding hearing request under this docket within 30 days. As of December 13, 2010, the company had not responded to FDA.

FDA was unable to find current contact information for American Therapeutics, Amide Pharmaceutical, Inc., Bay Laboratories, Inc., National Pharmaceutical Manufacturing Co., Pharmaceutical Basics, Inc., Superpharm Corp., and United States Trading Corp. FDA did not receive any response to its attempt to contact Carnrick Laboratories, a subsidiary of Elan Corporation; Copley Pharmaceutical, Inc.; LuChem Pharmaceuticals, Inc.; Pioneer Pharmaceuticals, Inc.; Quantum Pharmics, Ltd.; or Upsher-Smith Laboratories, Inc. If any of these companies, or their successors-in-interest, continue to have an interest in pursuing their hearing requests under this docket, the companies (or their successors-in-interest) must affirm their hearing requests in writing by the date specified in this notice. FDA will assume that hearing requests that are not affirmed within that time frame are no longer being pursued, and will deem them withdrawn.

### III. Discontinued Products

Some firms may have previously discontinued the manufacturing or distribution of products covered by this notice without removing them from the listing of their products under section 510(j) of the FD&C Act. Other firms may discontinue manufacturing or marketing listed products in response to this notice. Firms that wish to notify the agency of product discontinuation should send a letter, signed by the firm's chief executive officer, fully identifying the discontinued product(s), including NDC number(s), and stating that the product(s) has (have) been

discontinued. The letter should be sent to Sakineh Walther (*see ADDRESSES*).

Firms should also update the listing of their products under section 510(j) of the FD&C Act to reflect discontinuation of unapproved products. FDA plans to rely on its existing records, including drug listing records or other available information, when it targets violations for enforcement action. Firms should be aware that, after the effective date of this notice, FDA intends to take enforcement action without further notice against any firm that manufactures or ships in interstate commerce any unapproved product covered by this notice that is not the subject of an ongoing DESI proceeding.

### IV. Reformulated Products

Some of the active ingredients found in drug products covered by this notice are included in the OTC monograph in part 341 (21 CFR part 341), "Cold, Cough, Allergy, Bronchodilator, and Antihistamine Drug Products for Over-the-Counter Human Use." OTC products that comply with this monograph may be marketed without approval.

However, FDA cautions firms against reformulating products into OTC products or different unapproved new drugs that are marketed under the same name or substantially the same name (including a new name that contains the old name). Reformulated products marketed under a name previously identified with a different active ingredient or combination of active ingredients have the potential to confuse health care practitioners and harm patients.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sections 502 and 505 (21 U.S.C. 352 and 355), and under authority delegated to the Assistant Commissioner for Policy under section 1410.21 of the FDA Staff Manual Guide.

Dated: January 3, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0247]

#### FDA Transparency Initiative: Improving Transparency to Regulated Industry

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** As part of the third phase of the Transparency Initiative, the Food and Drug Administration (FDA) is announcing the availability of a report entitled "FDA Transparency Initiative: Improving Transparency to Regulated Industry." The report includes 19 action items and 5 draft proposals to improve transparency to regulated industry. FDA is seeking public comment on the content of the draft proposals, as well as on which draft proposals should be given priority.

**DATES:** Submit electronic or written comments by March 8, 2011.

**ADDRESSES:** 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. All comments should be identified with the docket number found in brackets at the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ann Witt, Office of Policy, Planning, and Budget, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 32, rm. 4226, Silver Spring, MD 20993, 301-796-7463, FAX: 301-847-8616, e-mail: [Ann.Witt@fda.hhs.gov](mailto:Ann.Witt@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

#### I. Background on the FDA Transparency Initiative

In January 2009, President Obama issued a memorandum on Transparency and Open Government calling for an "unprecedented level of openness in Government" and directing the Director of the Office of Management and Budget (OMB) to issue an Open Government Directive instructing executive departments and agencies to take specific actions to implement the principles of transparent, collaborative, and participatory government. The Open Government Directive was issued December 8, 2009. Under the leadership of Secretary of Health and Human Services, Kathleen Sebelius, the U.S. Department of Health and Human Services has also prioritized transparency and openness. In June 2009, the Commissioner of Food and Drugs (the Commissioner), Dr. Margaret Hamburg, launched FDA's Transparency Initiative to implement these efforts at FDA.

The initiative is overseen by a Task Force representing key leaders of FDA. The internal Task Force is chaired by the Principal Deputy Commissioner of FDA and includes five of the Agency's

center directors, the Chief Counsel, the Associate Commissioner of Regulatory Affairs, and the Chief Scientist. The Task Force is charged with submitting a written report to the Commissioner on the Task Force's findings and recommendations.

The Task Force has held two public meetings,<sup>1</sup> launched an online blog (<http://fdatransparencyblog.fda.gov/>), and opened a docket. The online blog and the docket received over 1,500 comments. The blog, which is ongoing, has offered an opportunity for exchange about specific ideas for transparency at the Agency.

The Task Force is proceeding with the Transparency Initiative in three phases:

- Phase I: FDA Basics.
- Phase II: Public Disclosure.
- Phase III: Transparency to

Regulated Industry.

Phase I is intended to provide the public with basic information about FDA and how the Agency does its work. In early January 2010, FDA launched a Web-based resource called *FDA Basics* (<http://www.fda.gov/fdabasics>). The resource now includes (1) 158 questions and answers about FDA and the products that the Agency regulates, (2) 9 short videos that explain various FDA activities, and (3) 14 conversations with FDA officials about the work of their offices. Each month, senior officials from FDA product centers and offices host online sessions about a specific topic and answer questions from the public about that topic. FDA uses the feedback provided by the public to update this resource.

Phase II relates to FDA's proactive disclosure of information the Agency has in its possession, and how to make information about Agency activities and decisionmaking more transparent, useful, and understandable to the public, while appropriately protecting confidential information. On May 19, 2010, FDA released a report that contains 21 draft proposals about expanding the disclosure of information by FDA while maintaining confidentiality for trade secrets and individually identifiable patient information.

The Task Force solicited comment on the content of the proposals, as well as on which draft proposals should be given priority, for 60 days. The Task Force is reviewing the comments received and will recommend specific proposals to the Commissioner for consideration. The Task Force's recommendations will consider

feasibility and priority, considering other Agency priorities that require resources. Not all of these proposals will necessarily be implemented. Some may require changes in law or regulation; some may require a substantial amount of resources.

Phase III is the subject of this document and is described in more detail in section II of this document.

## II. Phase III: Transparency to Regulated Industry

The third phase of the Transparency Initiative addresses ways FDA can become more transparent to regulated industry to foster a more efficient and cost-effective regulatory process.

Regulated industry provides the public with food, drugs, medical devices, cosmetics, and other widely used and important consumer products. FDA's mission is to protect and promote the public health through oversight of these products.

In order to succeed, FDA must clearly communicate standards and expectations to industry. Communicating requirements and expectations to industry in a more accessible manner promotes understanding of, and compliance with, rules set up to protect the supply of food and medical products.

In response to a request for input from FDA on this topic in March 2010 (75 FR 11893, March 12, 2010), regulated companies requested additional transparency about the standards to which their products are held, the process for soliciting guidance from the Agency, and the progress of regulatory efforts at the Agency. In the report, FDA outlines 19 action items and 5 draft proposals to improve transparency to regulated industry.

The Task Force is soliciting comment on the content of the five draft proposals, as well as on which draft proposals should be given priority, for 60 days. After considering public comment on the draft proposals, the Task Force will recommend specific proposals to the Commissioner for consideration. FDA will begin to implement the action items in the report in 2011.

## III. Request for Comments

FDA is interested in receiving comments from the public about the content of the five draft proposals as well as on which draft proposals should be given priority. 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. Identify the draft proposal which your comment addresses by the number assigned to that proposal. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 1, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-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 February 8, 2011, from 8 a.m. to 5 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 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 "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings". Please note that visitors to the White Oak Campus must enter through Building 1.

*Contact Person:* Nicole Vesely, 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: 301-847-8532, email: [nicole.vesely@fda.hhs.gov](mailto:nicole.vesely@fda.hhs.gov), or FDA

<sup>1</sup> Transcripts and the webcast from both public meetings are available on the FDA Web site, <http://www.fda.gov/transparency>.