

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic.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This draft guidance refers to previously approved collections of information found in FDA regulations.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 21 CFR part 312 have been approved under 0910-0014; 21 CFR part 601 have been approved under 0910-0338; CFR part 606 have been approved under 0910-0116; and 21 CFR part 7, subpart C, have been approved under 0910-0249.

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The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time.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may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.regulations.gov>.

Dated: April 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0226]

Risk Communication 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: Risk Communication Advisory Committee.

General Function of the Committee:

To provide advice and recommendations to the agency on effective risk communication.

Date and Time: The meeting will be held on May 15, 2008, from 8 a.m. to 5 p.m. and May 16, 2008, from 8 a.m. to 2 p.m.

Addresses: Submit electronic comments and information to <http://www.regulations.gov>. Comments are to be identified with the docket number found in brackets in the heading of this document. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of business on June 16, 2008. All comments received will be posted without change, including any personal information provided. Comments received on or before May 8, 2008, will be provided to the committee before or at the meeting; comments received after that time will still be considered in preparing the report that was specified in the FDA Amendments Act of 2007 (see docket and committee background for further information).

Location: Hilton Washington DC/ Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD, 20852-1699.

Contact Person: Lee L. Zwanziger, Office of the Commissioner, Office of Planning (HFP-60), Food and Drug Administration, 5600 Fishers Lane (for express delivery: rm. 15-22), Rockville, MD, 20857, 301-827-2895, FAX: 301-827-5340, Food and Drug

Administration, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 8732112560. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that affect 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: On May 15, 2008, the committee will meet for presentations and discussion of direct-to-consumer (DTC) advertising, including how it relates to communicating to subsets of the general population, such as the elderly, children, and racial and ethnic minority communities, and increased access to health information and decreased health disparities for these populations. On May 16, 2008, the committee will discuss studying the appropriateness of including, in televised DTC ads, a statement encouraging consumers to report negative side effects of prescription drugs to MedWatch, as is currently required for print DTC prescription drug ads.

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/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and 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 May 8, 2008. Written submissions may also be made to the docket at the address above (see the docket for further information on topics of particular interest for comment in connection with this meeting). Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on May 15th and between 10:30 a.m. and 11:30 a.m. on May 16th. Those desiring to make formal oral presentations should notify the contact person on or before May 8,

2008, and should 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. 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 May 9, 2008.

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 Lee L. Zwanziger 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/oc/advisory/default.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: April 18, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0238]

Determination That TAPAZOLE Tablets and 18 Other Drug Products Were 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 the 19 drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to the drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6308, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors 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. Sponsors of ANDAs 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 (the 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 generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn 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).

Under § 314.161(a) (21 CFR 314.161(a)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved or (2) whenever a listed drug is voluntarily withdrawn from sale, and ANDAs that refer to the listed drug have been approved. Section 314.161(d) provides that if FDA determines that a listed drug was removed from sale for safety or effectiveness reasons, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed. (As requested by the applicants, FDA withdrew approval of NDA 7-517 for TAPAZOLE Tablets in the **Federal Register** of November 7, 2007 (72 FR 62858), NDA 18-754 for ORUDIS Capsules in the **Federal Register** of June 16, 2006 (71 FR 34940), NDA 18-062 for PROVENTIL Syrup in the **Federal Register** of March 4, 2005 (70 FR 10651), and NDA 8-604 for PHENERGAN VC Syrup in the **Federal Register** of May 5, 2004 (69 FR 25124).

NDA No.	Drug	Applicant
7-517	TAPAZOLE (methimazole) Tablets, 5 milligrams (mg) and 10 mg	King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620
7-935	PHENERGAN (promethazine hydrochloride (HCl)) Tablets, 25 mg	Wyeth Pharmaceuticals, Inc., P.O. Box 8299, Philadelphia, PA 19101-8299
8-306	PHENERGAN with Codeine (codeine phosphate and promethazine HCl) Syrup, 6.25 mg/5 milliliters (mL), 10 mg/5 mL	ANI Pharmaceuticals, Inc., 7131 Ambassador Rd., Woodlawn, MD 21244