

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0356]

DDM
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Certifier D. Hawkins

**Behind the Counter Availability of Certain Drugs; Public Meeting; Comment
Period Clarification**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; comment period clarification.

SUMMARY: In the **Federal Register** of October 4, 2007 (72 FR 56769), the Food and Drug Administration (FDA) published a notice that announced a public meeting to obtain comments regarding behind-the-counter (BTC) availability of human drugs. An incorrect date was published in that notice. This document clarifies that Docket No. 2007N-0356 will close on December 17, 2007.

ADDRESSES: You may submit comments, identified by Docket No. 2007N-0356, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written registration and comments in the following ways:

- FAX: 301-827-6870.

- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions):
Division of Dockets Management (HFA-305), Food and Drug Administration,
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at <http://www.fda.gov/ohrms/dockets> approximately 30 days after the meeting.

FOR FURTHER INFORMATION CONTACT: Erik Mettler, Office of Policy (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360, FAX: 301-594-6777 Erik.Mettler@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 4, 2007 (72 FR 56769), FDA announced that it would hold a public meeting regarding BTC availability of certain human drugs. BTC availability could make certain drugs available behind the counter at the pharmacy without a prescription and require the intervention of a pharmacist before dispensing.

Some groups have asserted that pharmacist interaction with the consumer could ensure safe and effective use of a drug product that otherwise might require a prescription. Because pharmacists have the training and knowledge to provide certain interventions, they may be able to ensure that patients meet the conditions for use and educate patients on appropriate use of the drug product. These groups have suggested that the availability of certain drugs BTC could increase patient access to medications that may be underutilized, particularly by patients without health insurance, because these medications otherwise would be available only with a prescription.

The **Federal Register** notice stated that interested persons would be able to submit comments to the Division of Dockets Management and that the public docket would remain open for 30 days following the meeting. Our intent was to state that the docket would remain open until December 17, 2007 (30 days after the meeting, which occurred on November 14, 2007). However, the notice also instructed persons to register if they wished to attend or participate in the meeting; the instructions stated that registration would occur on a first-come, first-serve basis, but then mistakenly declared that written or electronic comments would be accepted “until November 28, 2007” (72 FR 56769).

II. Comments

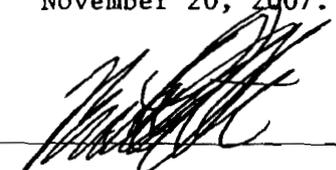
This notice clarifies that we will accept comments to the public docket until December 17, 2007.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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 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.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition

date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: 11/20/07
November 20, 2007.



Randall W. Lutter,
Deputy Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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Dawn P. Hawkins