

will be posted to the docket at <http://www.regulations.gov>.

*Transcripts:* Transcripts will not be provided.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Cardiovascular procedures are performed in hundreds of thousands of patients every year to treat all manner of cardiovascular disease from coronary artery disease to peripheral vascular disease, intracardiac ablation to surgical interventions, implant of stents to implants of pacemakers, defibrillators, and their associated leads. Information obtained from clinical trials is often limited due to small size, short followup, and lack of generalizability. Observational studies and registries have become increasingly important data sources for assessing the performance of cardiovascular therapeutic medical devices in the real-world setting. However, these registries are often limited in scope and size to a specific country, region, or health care provider system.

Developing a comprehensive understanding of the performance of these devices requires not only an indepth analysis across data sources to link device use to clinical outcomes, but also to incorporate data from international experience with these devices and procedures. FDA is holding this workshop to discuss the development of an international consortium of cardiovascular registries that would allow for broad-based analysis and surveillance of medical device exposure and related clinical outcomes. This effort follows on the successful model of the International Consortium of Orthopedic Registries (ICOR), which has developed a framework for distributed analysis across their member registries around the world. The development of a similar consortium of cardiovascular registries will begin with a narrowed scope incorporating transcatheter valve therapy devices and procedures.

At the end of this workshop, FDA intends that the participants and stakeholders will develop a comprehensive plan for the development of an operational international consortium of cardiovascular registries. This plan will identify specific issues that must be addressed and provide a "roadmap" for full implementation.

##### II. Topics

Topics to be discussed at this meeting include:

- The role of registry consortia in postmarket surveillance,

- Goals of the International Consortium of Cardiovascular Registries,
- Lessons learned from the development of the ICOR,
- Development of an international consortium of transcatheter valve registries as a pilot phase,
- Analysis of near- and long-term outcomes reported through registries, and
- Discussion of capabilities, challenges, and limitations of existing transcatheter valve registries.

Dated: March 27, 2013.

**Peter Lurie,**

*Acting Associate Commissioner for Policy and Planning.*

[FR Doc. 2013-07579 Filed 4-1-13; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2013-N-0001]

##### Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee: Notice of Change of Meeting Schedule

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Wednesday, February 27, 2013 (78 FR 13347). The meeting was shortened to one day, as it was later determined that in order to be more financially prudent all three topics could fit into one day.

**FOR FURTHER INFORMATION CONTACT:** Sara J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1611, Silver Spring, MD 20993-0002, [Sara.Anderson@fda.hhs.gov](mailto:Sara.Anderson@fda.hhs.gov), 301-796-7047, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In FR doc. 2013-04543, appearing on page 13347 in the **Federal Register** of Wednesday, February 27, 2013, the following correction is made:

1. On page 13347, in the first column, under the section entitled "Date and Time", the date is corrected to be April 25, 2013.

2. On page 13347, in the second column, the section entitled "Agenda" is corrected to read as follows:

*Agenda:* On April 25, 2013, the committee will discuss and make recommendations on the appropriate regulatory classification for diagnostic devices known as methotrexate enzyme immunoassays. Methotrexate enzyme immunoassays are considered pre-Amendment devices since they were in commercial distribution prior to May 28, 1976, when the Medical Device Amendments became effective. Methotrexate enzyme immunoassays are currently regulated under the heading of "Enzyme Immunoassay, Methotrexate," Product Code LAO, as unclassified under the 510(k) premarket notification authority. Methotrexate enzyme immunoassays are for the quantitative determination of methotrexate. The measurements obtained are used in monitoring levels of methotrexate to ensure appropriate drug therapy. FDA is seeking panel input on the safety and effectiveness of methotrexate enzyme immunoassays.

The committee will also discuss and make recommendations on the appropriate regulatory classification for diagnostic devices known as phenacyclidine (PCP) enzyme immunoassays and PCP radioimmunoassays. PCP enzyme immunoassays and PCP radioimmunoassays are considered pre-Amendment devices since they were in commercial distribution prior to May 28, 1976 when the Medical Device Amendments became effective. PCP enzyme immunoassays are currently regulated under the heading of "Enzyme Immunoassay, Phenacyclidine," Product Code LCM, and "Radioimmunoassay, Phenacyclidine," Product Code LCL, as unclassified under the 510(k) premarket notification authority. FDA is seeking panel input on the safety and effectiveness of PCP enzyme immunoassays and PCP radioimmunoassays.

The committee will also discuss and make recommendations on the appropriate regulatory classification for diagnostic devices known as isoniazid test strips. Isoniazid test strips are considered pre-Amendment devices since they were in commercial distribution prior to May 28, 1976 when the Medical Device Amendments became effective. Isoniazid test strips are currently regulated under the heading of "Strip, Test Isoniazid," Product Code MIG, as unclassified under the 510(k) premarket notification authority. Isoniazid test strips are a qualitative assay used for detecting isonicotinic acid and its metabolites in

urine to determine compliance of isoniazid (INH) medication. FDA is seeking panel input on the safety and effectiveness of isoniazid test strips.

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 meeting link.

3. On page 13347, in the third column, the section entitled "Procedure" is corrected to read as follows:

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 April 16, 2013. On April 25, 2013, oral presentations from the public regarding Methotrexate Test Systems will be scheduled between approximately 9:15 a.m. and 9:45 a.m.; regarding phencyclidine (PCP) Test Systems between approximately 1:55 p.m. and 2:25 p.m.; and regarding Isoniazid Test Systems between approximately 4:15 p.m. and 4:45 p.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 April 8, 2013. 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 April 9, 2013.

Dated: March 27, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0341]

#### Modifications To Labeling of Nicotine Replacement Therapy Products for Over-the-Counter Human Use

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that we have concluded that certain statements set forth in the FDA-approved labels of over-the-counter nicotine replacement therapy products, related to concomitant use with other nicotine-containing products and duration of use, can be modified. In light of currently available evidence, these statements are no longer believed to be necessary in their current form to ensure the safe and effective use of over-the-counter nicotine replacement therapy products for their approved intended use as aids to smoking cessation. We encourage the submission of supplemental new drug applications (labeling supplements) to modify these statements as described in this notice.

**ADDRESSES:** Submit labeling supplements to the Center for Drug Evaluation and Research, Food and Drug Administration, Central Document Room (CDR), 5901-B Ammendale Rd., Beltsville, MD 20705-1266. Copies of the recommended revisions to product labeling may be requested from the Center for Drug Evaluation and Research's Division of Nonprescription Clinical Evaluation, 10903 New Hampshire Ave., Bldg. 22, Stop 5411, Silver Spring, MD 20993, 301-796-2080. Copies of published studies that can be used to support labeling supplements will be on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and can be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

#### FOR FURTHER INFORMATION CONTACT:

Doris J. Bates, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4417, Silver Spring, MD 20993, 301-796-1040, FAX: 301-796-9721, email: [doris.bates@fda.hhs.gov](mailto:doris.bates@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

## I. Background

### A. Smoking and Tobacco Dependence

Tobacco use is the leading preventable cause of death and disease in the United States. According to an estimate by the Centers for Disease Control and Prevention, cigarette smoking causes 443,000 deaths each year in the United States, including nearly 50,000 deaths per year from involuntary exposure to tobacco smoke (Ref. 1). Smoking is known to cause multiple cancers, heart disease, stroke, complications of pregnancy, chronic obstructive pulmonary disease, and many other diseases that, on average, shorten smokers' lifespans by 14 years (Ref. 2).

Surveys show that approximately 70 percent of current smokers want to stop smoking, and nearly half of all smokers make a quit attempt each year (Ref. 3). Unfortunately, dependence on nicotine—the primary addictive substance in tobacco—is a chronic disease that often requires repeated intervention and multiple quit attempts to overcome. As a result, only a small percentage of smokers successfully quit each year (Ref. 3).

### B. Over-the-Counter Nicotine Replacement Therapies

Nicotine replacement therapy (NRT) products are designed to help people stop smoking by supplying controlled amounts of nicotine to ease the withdrawal symptoms associated with a quit attempt. NRT products do not contain all of the carcinogens and other harmful constituents that are found in cigarette smoke. There are currently three types of NRT products approved by FDA for over-the-counter (OTC) use as smoking cessation aids: Nicotine gum, transdermal nicotine patch, and nicotine lozenge products.<sup>1</sup> The nicotine gum and patch products were originally approved through the new drug application (NDA) process between 1984 and 1992. Both the gum and the patch were initially available by prescription only; these products were switched from prescription to OTC status between 1996 and 2002. The nicotine lozenge and mini-lozenge were approved directly for OTC use in 2002 and 2009, respectively.

Currently, the FDA-approved labeling for OTC NRT products instructs consumers that they should stop smoking when they begin using the product and that they should not use

<sup>1</sup> A nicotine spray and a nicotine inhaler have also been approved as smoking cessation aids. However, these NRT products are available by prescription only and are therefore outside the scope of this notice.