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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0171]

Using Innovative Technologies and Other Conditions of Safe Use To Expand Which Drug Products Can Be Considered Nonprescription; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The U.S. Food and Drug Administration (FDA or the Agency) is announcing a public hearing to obtain input on a new paradigm we are considering. Under this paradigm, the Agency would approve certain drugs that would otherwise require a prescription for nonprescription use (also known as over-the-counter or OTC) under conditions of safe use. These conditions of safe use would be specific to the drug product and might require sale in certain pre-defined health care settings, such as a pharmacy. This public hearing is being held to obtain information and comments from the public on the feasibility of this paradigm and its potential benefits and costs.

DATES: Public Hearing: The public hearing will be held on March 22 and 23, 2012, from 9 a.m. to 4 p.m. The meeting may be extended or may end early depending on the level of public participation.

Presentations and Comments: Submit either electronic or written requests for oral presentations and comments by March 9, 2012. (See section IV of this document for details.) Either electronic or written comments will be accepted after the hearing until May 7, 2012. (See section VI of this document for details.)

ADDRESSES: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503, Silver Spring, MD, 20993–0002.
hyperlipidemia (high cholesterol), hypertension (high blood pressure), migraine headaches, and asthma. For instance, some consumers do not seek necessary medical care, which may include prescription drug therapy, because of the cost and time required to visit a health care practitioner for an initial diagnosis and an initial prescription. Some patients who obtain an initial prescription do not continue on necessary medication because they would need to make additional visits to a health care practitioner for a prescription refill after any refills authorized by the initial prescription have been used or the time during which they can be filled has expired. Some prescription medications require routine monitoring through the prescribing practitioner such as blood tests to assist in the diagnosis of a condition, or to determine whether or how well the medication is working, or to adjust the dose. FDA believes that some of these visits could be eliminated by making certain prescription medications available without a prescription but with certain other conditions of safe use that would ensure they could be used safely and effectively without the initial involvement of a health care practitioner. In some cases, a visit to a practitioner would be required for the initial prescription, but a certain number of refills could be authorized beyond those that would normally be authorized without a return visit under specialized conditions of safe use. This paradigm might be useful for certain rescue medicines, such as inhalers used for asthma or epinephrine for allergic reactions, that patients need to keep on hand for use in emergencies. In addition to improved health outcomes for consumers staying on their medications, the time and attention that physicians and other health care providers expend on routine tasks related to prescription refills reduces the time that they are available to attend to more seriously ill patients. Eliminating or reducing the number of routine visits could free up prescribers to spend more time on seriously ill patients, reduce the burdens on the already overburdened health care system, and reduce health care costs.

II. New Paradigm

FDA is considering whether medications for certain diseases or conditions that would otherwise be available only by prescription could be made available without a prescription with certain conditions of safe use. For example, some conditions of safe use could be designed to assist patients in self-selection of an appropriate medication or provide for followup monitoring during continued use. The conditions of use could include requiring pharmacist intervention to ensure appropriate nonprescription use. Additionally, conditions of safe use could involve the use of innovative technologies, such as diagnostics approved or cleared by FDA for use in the pharmacy or other setting. FDA is aware that industry is developing new technologies that could be designed to assist patients in obtaining information and public access to needed medications by developing new technologies that could be designed to assist patients in obtaining information and public access to needed medications by creating a pathway for nonprescription use.

III. Scope of the Public Hearing

FDA is seeking input on what types of evidence would be needed to demonstrate that certain drugs could be used safely and effectively in the nonprescription setting with conditions of safe use. We anticipate that, depending upon the situation, applications for approval of nonprescription products with conditions of safe use may need to include patient studies (e.g., self-selection studies, label comprehension studies, and actual use studies) to demonstrate that the drug would be safe and effective under the specified conditions. When a device, e.g., diagnostic test or computer algorithm, is necessary as a condition of safe use, evidence may need to be submitted demonstrating that it will perform its intended function and can be appropriately administered in the particular setting in which it will be used. We expect that certain classes of drugs may be appropriate candidates for nonprescription use under this new paradigm, but FDA would need to evaluate each NDA, and when applicable, each device, on a case-by-case basis.

A. Types of Technology and Conditions of Safe Use

1. Can you suggest specific medical conditions or diseases for which consumers may benefit if the treatment drug were available as a nonprescription product with conditions of safe use?

2. What types of technologies (e.g., kiosks, computer algorithms) are currently in development that could assist in allowing drugs to be used safely and effectively in the nonprescription setting?
3. What other types of conditions of safe use (e.g., pharmacy monitoring or counseling) could be used to help ensure the safe and effective use of certain drug products as nonprescription products?

4. Are there types of diagnostic aids, such as noninvasive blood pressure monitors and urinalysis reagent strips, that could be used in the nonprescription setting after appropriate FDA review, either with or without the aid of a pharmacist to diagnose or monitor a disease or condition?

5. What data or other information exist on the use of conditions of safe use, including novel technologies, and on their effects on health care, access to medication, and/or disease and treatment education or awareness?

6. Are there data on how expanded access to medication or increased consumer education or awareness could affect patient or consumer behavior (e.g., by promoting patient compliance with a medication dosage regimen) or on health outcomes generally that would be relevant to the discussion of expanding the availability of nonprescription medications with conditions of safe use?

7. What types of studies could be conducted to evaluate the effects of conditions of safe use on the safety and efficacy of particular drugs and on behavior and health outcomes?

8. What types of studies could be conducted to evaluate the safety and efficacy of any technologies that might be relevant to and inform our consideration of this paradigm (e.g., a collaborative practice agreement between a pharmacist and a practitioner that allows the pharmacist to dispense a prescription drug to a consumer who meets certain criteria under a standing or open prescription, when that consumer did not obtain a prescription directly from a practitioner, or that allows a pharmacist to refill a prescription after an initial prescription from a practitioner pursuant to a similar agreement)?

9. What experiences have practitioners, pharmacists, and insurers had with state-authorized arrangements under which access to prescription drugs has been expanded that might be relevant to and inform our consideration of this paradigm (e.g., a collaborative practice agreement between a pharmacist and a practitioner that allows the pharmacist to dispense a prescription drug to a consumer who meets certain criteria under a standing or open prescription, when that consumer did not obtain a prescription directly from a practitioner, or that allows a pharmacist to refill a prescription after an initial prescription from a practitioner pursuant to a similar agreement)?

10. What are the public health and regulatory implications of the use of in vitro diagnostic tests as conditions of safe use for nonprescription drug products in a pharmacy setting (e.g., as a laboratory under the Clinical Laboratory Improvement Act of 1988 (CLIA) (Public Law 100–578))?
are not present when called risk forfeiting their scheduled time.

If you need special accommodations due to a disability, contact Lee Lemley (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

V. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner and the relevant centers.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation (21 CFR 15.30(e)). Public hearings under part 15 are subject to FDA’s policy and procedures for electronic media coverage of FDA’s public administrative proceedings (part 10 (21 CFR part 10), subpart C) (§ 10.203(a)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA’s public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). (See section VII of this document for more details.) To the extent that the conditions for the hearing as described in this document conflict with any provisions set out in part 15, this document acts as a waiver of those provisions as specified in § 15.30(h)).

VI. Request for Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments for consideration. Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management. You should annotate and organize your comments to identify the specific questions identified by the topic to which they refer. It is only necessary to send one set of comments. Identify comments 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.

VII. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (see ADDRESSES). A transcript also will be available in either hard copy or on CD–ROM after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Office of Management Programs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.


Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration [Docket No. FDA–2012–N–0001]

Cardiovascular and Renal 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Cardiovascular and Renal 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 27, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, Building 31 Conference Center, the Great Room (rm. 1503), 10903 New Hampshire Ave., 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: Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–0001, email: CRDACS@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: On March 27, 2012, the committee will begin with a closed session from 8 a.m. to 10:45 a.m. Following the closed session, from 11 a.m. to 5 p.m., the meeting will be open to the public. The committee will discuss biologics license application 125410, proposed tradename REPLAGAL (agalsidase alfa), submitted by Shire Human Genetics Therapies, for an enzyme replacement therapy for patients with Fabry disease.

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: On March 27, 2012, from 11 a.m. to 5 p.m., the meeting is open to the public. 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 13, 2012. Oral presentations from the public will be scheduled between approximately 2:10 p.m. and 3:10 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 March 5, 2012. Time allotted