Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per respondent (in hours)	Total annual burden in hours
Total					1735

Kimberly S. Lane,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2012–4566 Filed 2–27–12; 8:45 am]

BILLING CODE 4163–18–P

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.

Comments and Transcripts: Submit either electronic or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.* All comments should be identified with the docket number found in brackets in the heading of this document. Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 45 days after the hearing.

FOR FURTHER INFORMATION CONTACT: Lee Lemley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903–0002, 301–796–3441, Fax: 301–847–8753, email: *OTCTechnologiesPublicMeeting@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing a public hearing to obtain input on a potential new paradigm under which the Agency would approve certain drugs that would otherwise require a prescription for nonprescription use under conditions of safe use specific to the drug product. Some drugs approved in this manner might require sale in certain pre-defined health care settings, such as a pharmacy.

I. Background

A. Prescription and Nonprescription Drugs

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA approves new drugs under section 505 (21 U.S.C. 355) either as prescription or nonprescription. Under section 503(b)(1)(A) of the FD&C Act (21 U.S.C. 353(b)(1)(A)), a drug must be dispensed by prescription if, ''because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [it] is not safe for use except under the supervision of a practitioner licensed by law to administer such drug.'' Under sections 505(d)(1) and (d)(4), FDA has considerable latitude in determining whether the information submitted as part of a new drug application (NDA) is sufficient to ensure that a drug is safe for use under its proposed labeling. FDA also makes a determination under 503(b) as to whether the product meets the criteria for prescription-only dispensing.

Prescription drugs are dispensed upon receipt of a prescription from a practitioner licensed by law to administer the drug (which may include health care professionals such as physicians, nurse practitioners, physician's assistants, and others whom we will refer to here as practitioners or prescribers). (See 21 U.S.C. 353(b).) In many instances, under the current regulatory system, a patient has to obtain at least the initial prescription, and in some cases, prescription refills, from a practitioner through an in person interaction. Obtaining a refill for other prescription drugs involves at least a telephone call or other communication with the practitioner. In contrast, nonprescription drugs (sometimes referred to as over-the-counter or OTC products) can be purchased by consumers in pharmacies, supermarkets, and other retail establishments without the need for a prescription. Currently, consumers can purchase nonprescription drugs from a retailer for diseases or conditions that do not meet the statutory criteria for prescription products and that are safe and effective for use in self-medication as directed in the labeling. (See 21 U.S.C. 353(b).) Generally, OTC products: (1) Are available to treat diseases or conditions that can be self-diagnosed without a prior interaction with a practitioner, (2) are not associated with toxicities that require an evaluation of the benefits and risks by a practitioner; and (3) do not require a practitioner's input for use.

B. Undertreatment of Diseases and Other Effects on the Health Care System

Undertreatment of many common diseases or conditions in the United States is a well recognized public health problem. Increasing the number of people who are able to obtain for the first time and those who continue on necessary drug therapy could provide improved health outcomes. The requirement to obtain a prescription for appropriate medication (and to make one or more visits to a practitioner) may contribute to undertreatment of certain common medical conditions including

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 to treat 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 time with more 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 consumers could use to self-screen for a particular disease or condition and determine whether a particular medication is appropriate for them. For example, kiosks or other technological aids in pharmacies or on the Internet could lead consumers through an algorithm for a particular drug product. Such an algorithm could consist of a series of questions that help consumers properly self-diagnose certain medical conditions, or determine whether specific medication warnings contraindicate their use of a drug product. In addition, for some drug products that require an initial prescription, the product could be made available as a nonprescription product with a condition of safe use for the purpose of product refills.

In addition, some drug products that would otherwise require a prescription could be approved as nonprescription drug products with some type of pharmacist intervention as their condition of safe use. For example, some diseases or conditions might require confirmation of a diagnosis or routine monitoring using a diagnostic test (e.g., a blood test for cholesterol levels or liver function) that could be available in a pharmacy. A pharmacist, or consumer, could then use the results to determine whether use of a certain drug product is appropriate. Other potential roles for the pharmacist include assessing whether the consumer has any conditions or other risk factors that would indicate that the drug should not be used, or assisting the consumer in choosing between various drug products. For drugs that require use of a diagnostic test, creating a pathway for nonprescription use may result in the development by industry of diagnostics suitable for use by the patient or a pharmacy professional.

FDA is also considering whether the same drug product could be simultaneously available as both a prescription and nonprescription product with conditions of safe use. Dual availability could help ensure greater access to needed medications by making obtaining them more flexible. Consumers could choose to continue seeing their health care practitioner to diagnose diseases or conditions and obtain prescriptions, and when their local retail establishment is not equipped to offer the nonprescription product with conditions of safe use. Other consumers could take advantage of the ability to obtain nonprescription products with conditions of safe use where they are available.

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.

III. Scope of the Public Hearing

FDA is holding this public hearing to seek input from interested members of the public including consumers, pharmacists, physicians and other members of the medical community, regulated industry, insurers, and managed care organizations on a potential new paradigm to allow certain drugs that would otherwise require a prescription to be approved as nonprescription drugs with conditions of safe use. FDA is interested in obtaining information and public comment on the following issues:

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 relied upon as conditions of safe use?

B. Pharmacy, Consumer, and Health Care Provider Issues

1. Would this new paradigm increase consumer access to necessary medical care?

2. Are data available about the number of consumers who require drug therapy for conditions or diseases but who currently do not take such medication because of the burdens associated with obtaining a prescription?

3. Would a lack of oversight from a practitioner, including involvement in diagnosing the condition or monitoring for drug interactions or other drug effects, be a concern? If so, how could these concerns be addressed?

4. How might the new paradigm be expected to affect consumers financially or otherwise affect access to and delivery of health care generally?

5. Would expanding what could be considered nonprescription drugs under the new paradigm, and thus creating greater consumer access to needed drug products, reduce burden on emergency rooms and on individual health care providers, or otherwise increase the availability of these resources for other consumers? Are there other ways in which the new paradigm might reduce the burden on the health care system?

6. How might various types of conditions of safe use on nonprescription drug products affect pharmacy business operations? What differences might there be in the operational issues experienced by pharmacies operated by chains and independently operated retail outlets?

7. Would additional specialized training be needed for pharmacists if this paradigm were adopted?

8. If availability of a nonprescription product with conditions of safe use were limited to certain outlets (e.g., a chain pharmacy that chooses to offer a particular technology or service), would the situation create confusion or difficulties for consumers seeking to obtain the drug product? Could such a situation create difficulties for practitioners in knowing whether a particular consumer could access the drug with a prescription or would be able to obtain the same product as a nonprescription drug product at a retail outlet? If so, how could these issues be overcome?

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))?

C. Other Related Issues

1. How would insurance coverage of pharmaceuticals be affected by approving nonprescription products with conditions of safe use for widely prescribed prescription drugs under this paradigm?

2. How would out-of-pocket costs for the insured be affected by making prescription drugs available as nonprescription products with conditions of safe use?

3. Would the new paradigm increase liability concerns for pharmacists and pharmacies? To what extent would these concerns raise the cost of the services provided?

4. What proprietary, technological, economic, or competitive barriers might impede widespread implementation of this paradigm? To the extent such impediments exist, are there suggestions for mitigating or avoiding the impediments specific to this paradigm?

5. Would overall health care costs decrease if this paradigm were instituted?

IV. Attendance and/or Participation in the Public Hearing

The public hearing is free and seating will be on a first-come, first-served basis. Attendees who do not wish to make an oral presentation do not need to register.

If you wish to make an oral presentation during the hearing, you must register by submitting either an electronic or a written request by 5 p.m. on March 9, 2012, to Lee Lemley (see **FOR FURTHER INFORMATION CONTACT**). You must provide your name, title, business affiliation (if applicable), address, telephone and fax numbers, email address, and type of organization you represent (e.g., industry, consumer organization). You also should submit a brief summary of the presentation, including the discussion topic(s) that will be addressed and the approximate time requested for your presentation. We encourage individuals and organizations with common interests to consolidate or coordinate their presentations to allow adequate time for each request for presentation. Persons registered to make an oral presentation should check in before the hearing.

Participants should submit a copy of each presentation to Lee Lemley (see **FOR FURTHER INFORMATION CONTACT**) no later than March 19, 2012. We will file the hearing schedule, indicating the order of presentation and the time allotted to each person, with the Division of Dockets Management (see **ADDRESSES**). Additional information will also be available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm289290.htm.*

We will mail, email, or telephone the schedule to each participant before the hearing. In anticipation of the hearing presentations moving ahead of schedule, participants are encouraged to arrive early to ensure their designated order of presentation. Participants who

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.

Dated: February 23, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4597 Filed 2–27–12; 8:45 am]

BILLING CODE 4160–01–P

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, 301–796–9001, FAX: 301–847–8533, email: *CRDAC@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