

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

FD&C Act sections 512 (b)(2) and (n)(1)	FDA Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Phased Review with Administrative ANADA	356v	3	5	15	31.8	477
Total						3,339

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimates on our experience with ANADA submissions and requests for phased review. We estimate that we will receive 21 ANADA submissions per year over the next three years and that three of those submissions will request phased review. We estimate that each applicant that uses the phased review process will have approximately five phased reviews per application. We estimate that an applicant will take approximately 159 hours to prepare either an ANADA or the estimated 5 ANADA phased review submissions and the administrative ANADA.

Dated: May 5, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-1092]

Over-the-Counter Monograph User Fees: Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to gather stakeholder input on the potential development of a user-fee program for nonprescription (over-the-counter or OTC) monograph drugs. A user-fee program would provide funding to supplement congressional non-user-fee appropriations, and would support timely and efficient FDA review of the efficacy and safety of ingredients included in or proposed for inclusion in a monograph. FDA invites public comment on a potential OTC monograph user-fee program and also invites suggestions regarding the

features such a user-fee program should include.

DATES: The public meeting will be held on Friday, June 10, 2016, from 9 a.m. to 5 p.m. EDT. However, depending on the level of public participation, the meeting may be extended or may end early.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, Bldg. 31 Conference Center, 10903 New Hampshire Ave., the Great Room (Rm. 1503A), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information refer to <http://www.fda.gov/aboutfda/workingatfda/buildingsandfacilities/whiteoakcampusinformation/ucm241740.htm>.

Comments: Regardless of participation at the public meeting, interested persons may submit electronic or written comments regarding this document. To provide adequate time for parties to submit comments before and after the public meeting, the docket will remain open 30 days after the public meeting.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that

identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

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

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-1092 for "Over-the-Counter Monograph User Fees: Public Meeting; Requests for Comments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>.

www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> 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.

FOR FURTHER INFORMATION CONTACT: Amy Bertha, Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903-0002, 301-796-1647, email: OTCMonographUserFeeProgram@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public meeting to obtain input on a potential OTC monograph user-fee program. The Prescription Drug User Fee Act (PDUFA) and other FDA user-fee programs for medical products provide vital resources that have enabled more timely evaluation of the safety and efficacy of many prescription drugs, biologics and devices, with consequent benefits to public health through the expanded availability of products to treat and manage a wide variety of conditions. However, no user-fee program exists for hundreds of thousands of drug products marketed under OTC drug monographs. Millions of American consumers every year use monograph drug products to self-manage numerous conditions. The efficacy and safety of these drugs is important to public health, but FDA is critically under-resourced in this regulatory area.

In the United States, OTC drugs are marketed in two different ways—under

an approved marketing application (new drug application (NDA) or abbreviated new drug application (ANDAs)) or under the OTC monograph system, which was set up to review the safety and efficacy of drug products that were marketed OTC in the United States prior to the current statutory NDA process. When sponsors submit marketing applications, FDA reviews these applications and approves those drugs that are found to be safe and effective under their proposed conditions of use with benefits that outweigh their risks. However, at the time of establishment of the statutory efficacy requirement, there were hundreds of thousands of OTC products on the market. Withdrawing all those products and requiring submission of a new drug application for each one was undesirable for public health, and would have resulted in an overwhelming number of individual applications for review. Instead, in 1972, FDA established the OTC drug review process. In that process, expert advisory review panels were established to evaluate evidence of safety and efficacy for ingredients in broad therapeutic classes of OTC drug products. These panels reviewed data submissions and provided reports to FDA. Those reports made recommendations regarding whether or not the ingredients were “generally recognized as safe and effective (GRASE)” for use in self-treatment. The review panels also reviewed claims and recommended appropriate labeling. Based on the panels’ reviews, FDA published in the **Federal Register** advanced notices of proposed rulemaking and, after additional Agency review and public comment, tentative final monographs. Subsequently, final regulations in the form of individual drug monographs were established for various therapeutic areas; these monographs establish conditions of use under which ingredients are considered GRASE for inclusion in an OTC drug. Conditions of use can include, for example, indications for use, dosage form, and route of administration. Products that conform to all applicable regulations, including all aspects of the relevant monograph, will be GRASE and not misbranded if marketed without an approved marketing application. GRASE determinations were made, and monographs proposed and finalized, for many ingredients for many drug products. However, the process has not been completed for all ingredients, nor for all OTC conditions of use. In many cases, the data submitted to the advisory panels were inadequate for a final GRASE determination; these ingredients

are referred to as “Category III” ingredients in OTC products. Many products containing Category III ingredients without a GRASE determination continue to be marketed. By contrast, ingredients with a final determination of “not GRASE” need an approved marketing application to be legally marketed.

The OTC monograph drug review process remains one of the largest and most complex regulatory programs ever undertaken at FDA. There are approximately 88 simultaneous rulemakings in 26 broad therapeutic areas encompassing hundreds of thousands of products. There are approximately 800 active ingredients for over 1,400 different therapeutic uses. FDA needs additional resources to work toward finalization of the monograph review process and to address safety issues in a more efficient and timely manner. Additional resources would also better enable the Agency to consider innovations for drug products containing monograph ingredients, such as the development of new dosage forms for ingredients under existing monographs.

There are some important differences between marketing through approved applications and marketing under the monographs. NDAs and ANDAs are product-based; an application typically is submitted with data for a single drug product to be marketed by a single sponsor, and that application will be approved or not approved. By contrast, the monograph system is ingredient-based; numerous sponsors may make the same ingredient for the same use, and all may market drug products made with this ingredient as long as they comply with all applicable regulations, including the conditions of the monograph. Sponsors of monograph drugs are not required to seek FDA approval prior to marketing a product under the monograph. In addition, the monograph system, where ingredients are determined to be GRASE or not, is a public process. Data are submitted to public dockets, and anyone may provide input. By contrast, while FDA typically makes NDA information public after approval of a product, it generally cannot do so before.

At this time, once a monograph has been established, additional rulemaking is required for changes to that monograph. FDA is working on multiple policy reforms to streamline and modernize the monograph system; those policy reforms are not the topic of this public meeting. Funds from other user-fee programs cannot be used to fund monograph activities, and FDA receives

very few resources that it can allocate to monograph review work.

The potential benefits of additional resources from a monograph user-fee program include benefits to public health and sponsors of monograph drug products, such as the following:

- Ability to address safety issues of currently marketed products in an efficient and timely manner.
- Timely determination on the safety and efficacy of monograph ingredients under the conditions of the monograph, helping to assure appropriate marketing of thousands of nonprescription products used daily by U.S. consumers.
- Increased availability of certain monograph product innovations proposed by industry.
- Streamlined ability to update monographs to allow modern testing methods in several areas, potentially reducing the need for animal testing, and simplifying and speeding product development.
- Development of information technology infrastructure to speed numerous parts of the monograph review process, and enable a modern robust system for submission of materials and archiving of documents.
- Development of a modern, useful, and transparent FDA monograph Web site to provide the public and industry with access to important information.
- Ability to hold more public meetings on important monograph issues.
- Increased ability of FDA to respond to monograph-related concerns and questions from the public and industry.
- Establishment of additional infrastructure for the efficient continued conduct of monograph activities in the longer term.

II. Purpose of Public Meeting

The purpose of the meeting is to obtain input from industry and other interested stakeholders regarding a potential OTC monograph user-fee program. There are several factors that FDA considers important in developing a user-fee program. First, to achieve a program's goals of efficient and timely oversight of a category of products, FDA must be able to rely on a stable and predictable source of adequate funding. Funding sources that result in unpredictable revenue cause uncertainty about FDA's ability to continue supporting activities over time which disrupts the Agency's regulatory operations and contributes to difficulties in conducting long-range planning. Second, the assessment of fees can create certain incentives or disincentives for the activity that is the subject of the fee. For example, a

sponsor who currently has an unmarketed product has an incentive to pay a fee to seek FDA approval to market the product. However, once the product is approved and marketed, there is less incentive to pay a fee for additional specific activities regarding the product that are otherwise not required. If those activities are important from a public health perspective, assessing a fee for them would be undesirable because the fee could discourage entities to undertake those activities. With these considerations in mind, FDA seeks input on the following questions and welcomes any other relevant information the public would like to share.

- What types of user fees (e.g. product listing fees, facility fees, application fees, other types of fees) might be appropriate for a potential monograph user-fee program? Consider the following in your answer:

- For monograph products (unlike for products currently covered by user-fee programs), premarket applications are not generally submitted, and thus the approach regarding application-based fees might be expected to be different for a monograph user fee program compared to other user fee programs.

- Desirable industry activities or behavior that might be discouraged by the assessment of fees.

- The stability and predictability of the funding provided by the user-fee type.

- In conjunction with receiving user fees, FDA typically commits to certain performance goals related to the Agency's activities with respect to the relevant products. What types of performance goals might be important to consider from a public health and sponsor perspective? What parameters could be measured to gauge the success of a user-fee program?

III. Meeting Attendance and Participation

The public meeting is free and seating will be on a first-come, first-served basis. FDA is seeking participation (*i.e.*, attendance and oral presentations) at the public meeting by all interested parties. In general the meeting format may include, but will not be limited to, presentations by FDA staff, scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and representatives of the OTC monograph industry. If you wish to attend the public meeting either in person or by viewing the web cast, FDA asks that you please register through Eventbrite by Tuesday, May 31, 2016, in order for

FDA to estimate the number of attendees (<https://www.eventbrite.com/e/over-the-counter-monograph-user-fees-public-meeting-tickets-21565448838>).

If you wish to make an oral presentation at the public meeting, you must register through Eventbrite by Tuesday, May 31, 2016 (<https://www.eventbrite.com/e/over-the-counter-monograph-user-fees-public-meeting-tickets-21565448838>). FDA encourages individuals and organizations with common interests to coordinate and give a joint, consolidated presentation. FDA will try to accommodate all persons who wish to make a presentation; however, FDA may limit both the number of participants from individual organizations and the total number of attendees based on space and time limitations. FDA will notify registered presenters of their scheduled presentation times. Persons registered to speak should check in before the meeting and are encouraged to arrive early to ensure their designated order of presentation. Participants who are not present when called may not be permitted to speak at a later time. FDA will post an agenda of the public meeting and other background material at least 3 days before the public meeting and additional information will be available at: <http://www.fda.gov/Drugs/NewsEvents/ucm499390.htm>.

This public meeting will be web cast and the URL will be posted at <http://www.fda.gov/Drugs/NewsEvents/ucm499390.htm> at least 1 day before the meeting. A video record of the public meeting will be available at the same Web site address for 1 year. If you need special accommodations because of disability, please contact Amy Bertha (see **FOR FURTHER INFORMATION CONTACT**) no later than Friday, May 27, 2016.

IV. 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 (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>.

Dated: May 5, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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