

we expect that about 5% of participants taking the pre-choice survey will not return to participate in the experiment one week later, the number of respondents initially required is 5% higher (1,575) than the full sample of 1,500 required for the experiment. We estimate based on our previous

experience with the SelectMD 1.0 experiment that participants will require about 10 minutes to review the information on the Web site and select their preferred physician from the set of doctors available. The average time required to complete the post-choice survey is estimated to be 20 minutes.

Consequently, respondents will average about 40 minutes completing all three phases of the study.

Exhibit 2 shows the respondents' cost burden for their time to participate in this experiment. The total cost burden is estimated to be \$22,297.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hour per response (min/60)	Total burden hours
Pre-Choice Survey	1575	1	10/60	263
Time on Website (Choosing MD)	1500	1	10/60	250
Post-Choice Survey	1500	1	20/60	500
Total Hours	4,575	na	na	1,013

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Pre-Choice Survey	1575	263	\$22.01	\$5,789
Time on Website (Choosing MD)	1500	250	22.01	5,503
Post-Choice Survey	1500	500	22.01	11,005
Total Cost				22,297

* Based upon the national mean hourly wage for all occupations from the "May 2012 Occupational Employment and Wage Estimates", U.S. Department of Labor, Bureau of Labor Statistics.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: April 9, 2014.

Richard Kronick,
AHRQ Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0374]

Postmarketing Requirements for the Class-Wide Extended-Release/Long-Acting Opioid Analgesics; 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 obtain stakeholder input on the design and conduct of the postmarketing requirements (PMRs) for the class-wide extended-release/long-acting (ER/LA) opioid analgesic drug products to further assess the serious risks of misuse, abuse, hyperalgesia, addiction, overdose, and death associated with their long-term use.

FDA is seeking input on these issues from stakeholders, including patients, academia, researchers, State and other Federal regulators, health care organizations, health care providers, the pharmaceutical industry, and others from the general public.

DATES: The public meeting will be held on May 19 and 20, 2014, from 8 a.m. to

5 p.m. Individuals who wish to present at the meeting must register by May 9, 2014. See section III under the **SUPPLEMENTARY INFORMATION** section for information on how to register to speak at the meeting.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Participants must enter through Building 1 and undergo security screening. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Submit either electronic or written comments by June 19, 2014. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Janelle Derbis, Center for Drug Evaluation and Research, Food and Drug Administration, 20 North Michigan Ave., Suite 510, Chicago, IL 60602, 312-596-6516, FAX: 312-886-

1682, email: ERLAApioidPMRMeeting@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is committed to improving the safe and appropriate use of ER/LA opioid analgesics and preserving appropriate access for those patients who rely on these medications to manage their pain. In May 2012, FDA hosted a scientific workshop to discuss the assessment of analgesic treatment of chronic pain, during which presenters raised concerns about the safe and appropriate use of opioid analgesics.¹ Over the past 2 years, FDA has reviewed numerous submissions to Agency dockets, including citizen petitions and comments to petitions, and relevant literature about the benefits and risks associated with opioid drug products, including the serious risks of misuse, abuse, hyperalgesia, addiction, overdose, and death associated with the long-term use of ER/LA opioid analgesics. FDA has concluded that more data are needed regarding these serious risks.

FDA described these data requirements in its September 10, 2013, letter to all new drug application (NDA) applicants for ER/LA opioid analgesics. Data are needed to address the following issues:

- The incidence of and risk factors for misuse, abuse, addiction, overdose, and death associated with long-term use of opioids for chronic pain.
- Validated measures of misuse, abuse, addiction, overdose, and death.
- Validated coded medical terminologies used to identify misuse, abuse, addiction, overdose, and death.
- Validated definitions of “doctor/pharmacy shopping” as outcomes suggestive of misuse, abuse, and addiction.
- The serious risk of developing hyperalgesia following use of ER/LA opioid analgesics for at least 1 year to treat chronic pain.

In the September 10, 2013, letter, FDA informed the ER/LA opioid analgesic NDA application holders of the requirement to conduct postapproval studies (also referred to as postmarketing requirements or PMRs) and established milestone dates for completion of those studies, which include observational studies and a clinical trial (see section II for more

details). The deadline for the applicants’ final protocol submissions is August 2014.

II. Purpose and Scope of Meeting

The purpose of this public meeting is to obtain stakeholder input on the design and conduct of the PMRs (described in the following paragraph) for the ER/LA opioid analgesic drug products to assess the serious risks of misuse, abuse, hyperalgesia, addiction, overdose, and death associated with their long-term use. FDA and NDA applicants will consider stakeholder input when preparing final protocols to be submitted by August 2014.

The PMRs described in FDA’s September 10, 2013, letter to NDA applicants of ER/LA opioid analgesics are as follows:

- (1) PMR # 2065–1: Conduct one or more studies to provide quantitative estimates of the serious risks of misuse, abuse, addiction, overdose, and death associated with long-term use of opioid analgesics for management of chronic pain among patients prescribed ER/LA opioid products. Include an assessment of risk relative to efficacy.

These studies should address at a minimum the following specific aims:

- a. Estimate the incidence of misuse, abuse, addiction, overdose, and death associated with long-term use of opioids for chronic pain. Stratify misuse and overdose by intentionality wherever possible. Examine the effect of product/formulation, dose and duration of opioid use, prescriber specialty, indication, and other clinical factors (e.g., concomitant psychotropic medications, personal or family history of substance abuse, and history of psychiatric illness) on the risk of misuse, abuse, addiction, overdose, and death.
- b. Evaluate and quantify other risk factors for misuse, abuse, addiction, overdose, and death associated with long-term use of opioids for chronic pain, including, but not limited to, the following: Demographic factors, psychosocial/behavioral factors, medical factors, and genetic factors. Identify confounders and effect modifiers of individual risk factor/outcome relationships. Stratify misuse and overdose by intentionality wherever possible.

- (2) PMR # 2065–2: Develop and validate measures of the following opioid-related adverse events: Misuse, abuse, addiction, overdose, and death (based on the Department of Health and Human Services’ definition, or any agreed upon definition), which will be used to inform the design and analysis for PMR # 2065–1 and any future

postmarketing safety studies and clinical trials to assess these risks. This can be achieved by conducting an instrument development study or a validation study of an algorithm based on secondary data sources.

- (3) PMR # 2065–3: Conduct a study to validate coded medical terminologies (e.g., ICD9, ICD10, and SNOMED) used to identify the following opioid-related adverse events: Misuse, abuse, addiction, overdose, and death in any existing postmarketing databases to be employed in the studies. Stratify misuse and overdose by intentionality wherever possible. These validated codes will be used to inform the design and analysis for PMR # 2065–1.

- (4) PMR # 2065–4: Conduct a study to define and validate “doctor/pharmacy shopping” as outcomes suggestive of misuse, abuse, and addiction. These validated codes will be used to inform the design and analysis for PMR # 2065–1.

- (5) PMR # 2065–5: Conduct a clinical trial to estimate the serious risk for the development of hyperalgesia following use of ER/LA opioid analgesics for at least 1 year to treat chronic pain. We strongly encourage you to use the same trial to assess the development of tolerance following use of ER/LA opioid analgesics. Include an assessment of risk relative to efficacy.

III. Attendance and Registration

Attendance is free and will be on a first-come, first-served basis. Individuals who wish to present at the public meeting must register on or before May 9, 2014, at <https://erlaopioidpmrmeeting.eventbrite.com>. In section II, FDA has listed the PMRs. You should identify which PMR(s) you wish to address in your presentation, or whether your comments apply to all PMRs, so FDA can consider that in organizing the presentations. FDA will do its best to accommodate requests to speak and will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. An agenda and additional meeting background material will be available approximately 2 weeks before the meeting at <http://www.fda.gov/Drugs/NewsEvents/ucm384489.htm>.

Individuals who wish to attend the meeting but do not wish to make a presentation should register by May 12, 2014. Onsite registration on the day of the meeting will be based on space availability.

If you need special accommodations due to a disability, please contact Janelle Derbis (see **FOR FURTHER**

¹ Assessment of Analgesic Treatment of Chronic Pain: A Scientific Workshop (see <http://www.fda.gov/Drugs/NewsEvents/ucm283979.htm>). Information and comments from that workshop are available at www.regulations.gov, Docket No. FDA-2012-N-0067.

INFORMATION CONTACT) at least 7 days in advance.

A live Web cast of this meeting will be viewable at <https://collaboration.fda.gov/opmr/> on the day of the meeting. A video record of the meeting will be available at the same Web address for 1 year.

IV. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. To ensure consideration, submit comments by June 19, 2014. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

V. Transcripts

As soon as possible after a transcript of the public meeting 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 will also be available in either hardcopy 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), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: April 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0398]

Eli Lilly and Company, et al.; Withdrawal of Approval of 3 New Drug Applications and 41 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing

approval of 3 new drug applications and 41 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective May 22, 2014.

FOR FURTHER INFORMATION CONTACT:

Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6366, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in table 1 in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1—REQUESTS TO WITHDRAW APPROVAL OF APPLICATIONS

Application No.	Drug	Applicant
NDA 050440	Keflet (cephalexin) Tablets	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285.
NDA 050614	Keftab (cephalexin hydrochloride) Tablets	Do.
NDA 050673	Ceclor CD (cefaclor) Tablets	Do.
ANDA 075457	Famotidine Tablets USP, 20 milligrams (mg) and 40 mg	Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26505-4310.
ANDA 075559	Butorphanol Tartrate Injection USP, 1 mg/milliliter (mL) and 2 mg/mL.	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045.
ANDA 075572	Buspirone HCl Tablets USP, 5 mg, 10 mg, and 15 mg	Nesher Pharmaceuticals (USA) LLC, 13910 St. Charles Rock Rd., Bridgeton, MO 63044.
ANDA 075594	Pamidronate Disodium for Injection, 30 mg/vial and 90 mg/vial.	Teva Parenteral Medicines, Inc., 19 Hughes, Irvine, CA 92618.
ANDA 075609	Doxazosin Mesylate Tablets, 1 mg, 2 mg, 4 mg, and 8 mg ...	Nesher Pharmaceuticals (USA) LLC.
ANDA 075613	Bupropion HCl Tablets, 75 mg and 100 mg	Sandoz Inc., 2555 W. Midway Blvd., Broomfield, CO 80038-0446.
ANDA 075627	Acyclovir Injection, 50 mg/mL	Teva Parenteral Medicines, Inc.
ANDA 075730	Thiotepa for Injection USP, 15 mg/vial and 30 mg/vial	Do.
ANDA 075793	Famotidine Tablets USP, 20 mg and 40 mg	Sandoz Inc.
ANDA 075847	Oxaprozin Tablets USP, 600 mg	Mylan Pharmaceuticals, Inc.
ANDA 075905	Famotidine Injection, 10 mg/mL	Hospira, Inc.
ANDA 075943	Etodolac Extended-Release Tablets, 400 mg, 500 mg, and 600 mg.	Sandoz Inc.
ANDA 075950	Fluvoxamine Maleate Tablets, 50 mg and 100 mg	Mylan Pharmaceuticals, Inc.
ANDA 076018	Amiodarone HCl Injection, 50 mg/mL	Bedford Laboratories, 300 Northfield Rd., Bedford, OH 44146.
ANDA 076042	Fluconazole Tablets, 50 mg, 100 mg, 150 mg, and 200 mg ..	Mylan Pharmaceuticals, Inc.
ANDA 076044	Potassium Chloride Extended-Release Tablets USP, 20 milliequivalents.	Nesher Pharmaceuticals (USA) LLC.
ANDA 076088	Amiodarone HCl Injection, 50 mg/mL	Bedford Laboratories.
ANDA 076193	Propafenone HCl Tablets, 150 mg, 225 mg, and 300 mg	Nesher Pharmaceuticals (USA) LLC.
ANDA 076259	Milrinone Lacate in 5% Dextrose Injection	Baxter Healthcare Corp., 25212 W. Illinois Route 120, Round Lake, IL 60073.
ANDA 076299	Amiodarone HCl Injection, 50 mg/mL	Bedford Laboratories.