



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

JUL 9 2013

Whe-Yong Lo, Ph.D.
Vice President R&D and Regulatory Affairs
Tedor Pharma Inc.
400 Highland Corporate Drive
Cumberland, RI 02864

Re: Docket No. FDA-2013-P-0303

Dear Dr. Lo:

This letter responds to your citizen petition received on March 13, 2013, requesting that the Food and Drug Administration (FDA) determine whether METADATE ER (methylphenidate hydrochloride (HCl)) extended-release tablet, 10 milligrams (mg), has been voluntarily withdrawn, discontinued, or withheld from sale for safety or efficacy reasons.

FDA has reviewed its records and determined that METADATE ER (methylphenidate HCl) extended-release tablet, 10 mg, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain METADATE ER (methylphenidate HCl) tablet, 10 mg, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-7577.

Sincerely,

Reena P. Raman
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

function of a Medicare enrollment application is to gather information from a provider, supplier or other entity that tells us who it is, whether it meets certain qualifications to be a health care provider, supplier or entity, where it practices or renders its services, the identity of the owners of the enrolling entity, and information necessary to establish correct claims payments. We are adding a new CMS-855 Medicare Registration Application, the CMS-855C: Medicare Enrollment Application for Registration of Eligible Entities That Provide Health Insurance Coverage Complementary to Medicare Part B. This Medicare registration application is to be completed by all entities that provide a complimentary health benefit plan and intend to bill Medicare as an indirect payment procedure (IPP) biller and the entity or health plan meets all Medicare requirements to submit claims for indirect payments. The entity must furnish the name of at least one authorized official, preferably the administrator of the health plan, who must sign this registration application attesting that the registering entity meets the requirements to register as an indirect payment procedure biller and will also abide by the requirements stated in the Certification & Attestation Statement in Section 10 of the application.

The CMS-855C will be submitted at the time the applicant first requests a Medicare identification number for the sole purpose of submitting claims under the "Indirect Payment Procedure (IPP)" for reimbursement, and when necessary to report any changes to information previously submitted. The application will be used by Medicare contractors to collect data to ensure the applicant has the necessary credentials to submit Medicare claims for reimbursement, including information that allows Medicare contractors to ensure that the entity and its owners and administrators are not sanctioned from the Medicare program, or debarred, suspended or excluded from any other Federal agency or program. *Form Number:* CMS-855(C) (OCN: 0938-New); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 440; *Total Annual Responses:* 440; *Total Annual Hours:* 500. (For policy questions regarding this collection contact Kim McPhillips at 410-786-5374.)

Dated: June 28, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013-16085 Filed 7-3-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-P-0303]

Determination That METADATE ER (Methylphenidate Hydrochloride) Extended-Release Tablet, 10 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that METADATE ER (methylphenidate hydrochloride (HCl)) extended-release tablet, 10 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for methylphenidate HCl extended-release tablet, 10 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT:

Reena Raman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6238, Silver Spring, MD 20993-0002, 301-796-7577.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to

publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

METADATE ER (methylphenidate HCl) extended-release tablet, 10 mg, is the subject of ANDA 40-306, held by UCB, Inc., and initially approved on October 20, 1999. METADATE ER is indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: Moderate-to-severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity.

In a letter dated November 4, 2011, UCB, Inc., notified FDA that METADATE ER (methylphenidate HCl) extended-release tablet, 10 mg, had been discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book.

Tedor Pharma Inc. submitted a citizen petition dated March 6, 2013 (Docket No. FDA-2013-P-0303), under 21 CFR 10.30, requesting that the Agency determine whether METADATE ER (methylphenidate HCl) extended-release tablet, 10 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that METADATE ER (methylphenidate HCl) extended-release tablet, 10 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that METADATE ER (methylphenidate HCl) extended-release tablet, 10 mg, was withdrawn for

reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of this product from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list METADATE ER (methylphenidate HCl) extended-release tablet, 10 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to METADATE ER (methylphenidate HCl) extended-release tablet, 10 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: June 28, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-16101 Filed 7-3-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0596]

Lung Cancer Patient-Focused Drug Development; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the public docket on lung cancer patient-focused drug development. In the *Federal Register* of June 5, 2013 (78 FR 33581), FDA announced an opportunity for public comment on this topic and explained that the comment period would close on July 29, 2013. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments to the docket by August 28, 2013.

ADDRESSES: 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 comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1199, Silver Spring, MD 20993-0003, 301-796-5003, email: graham.thompson@fd.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of June 5, 2013 (78 FR 33581), FDA announced an opportunity for public comment on lung cancer patient-focused drug development and explained that the comment period would close on July 29, 2013. The Agency is extending the comment period to allow interested persons additional time to submit comments.

As part of Patient-Focused Drug Development, FDA is gathering patient and patient stakeholder input on symptoms of lung cancer that matter most to patients and on current approaches to treating lung cancer. FDA is interested in patients' perspectives for the two main types of lung cancer (small-cell and non-small cell lung cancer) on the importance of disease symptoms, benefits of treatment approaches, and possible cancer treatment side effects. FDA is interested in receiving patient input that addresses the following questions.

Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients

1. For context, how long ago was your diagnosis of lung cancer? Is your cancer currently in only one area of the lung or has it spread to other parts of the lung or outside of the lungs?

2. Of all the symptoms that you experience because of your lung cancer, which one to three symptoms have the most significant impact on your daily life? (Examples may include pain, cough, shortness of breath, fatigue, voice hoarseness.)

3. Are there specific activities that are important to you but that you cannot do at all, or as fully as you would like, because of lung cancer? (Examples may

include sleeping through the night, climbing stairs, household activities.)

Topic 2: Patients' Perspectives on Current Approaches To Treating Lung Cancer

1. Are you currently undergoing any cancer treatments to help reduce or control the spread of your lung cancer? Please describe.

1.1 What do you consider to be the most significant downsides of these treatments? (Examples of downsides may include side effects, going to the hospital for treatment, frequent blood tests, etc.)

1.2 How do these downsides affect your daily life?

2. What supportive care treatments, if any, are you taking to help improve or manage the symptoms you experience because of your lung cancer? Please include any prescription medicines, over-the-counter products, and other therapies including non-drug therapies (such as breathing techniques).

2.1 What specific symptoms do your treatments address?

2.2 How well do these treatments manage these symptoms?

2.3 Are there symptoms that your current treatment regimen does not address at all, or does not treat as well as you would like?

3. When thinking about your overall goals for treatment, how do you weigh the importance of prolonging your life versus improving the symptoms you experience because of your lung cancer?

4. What factors do you take into account when making decisions about using treatments to help reduce or control the spread of your lung cancer? In particular:

4.1 What information on the potential benefits of these treatments factors most into your decision? (Examples of potential benefits from treatments may include shrinking the tumor, delaying the growth of the tumor, prolonging life, etc.)

4.2 How do you weigh the potential benefits of these treatments versus the common side effects of the treatments? (Common side effects could include nausea, loss of appetite, fatigue, diarrhea, rash.)

4.3 How do you weigh potential benefits of these treatments versus the less common but serious risks associated with the treatments? (Examples of less common but serious risks are developing a hole in the stomach or intestine, liver failure, kidney failure, lung inflammation, blood clot, stroke, heart attack, serious infections, etc.)