

associated with both a physical and psychological burden. Nerve damage can be caused by diseases such as diabetes, physical injury, or exposure to drugs or toxins. The pain associated with neuropathies of sensory nerves may be characterized as a pins and needles sensation, as sharp, jabbing, or burning, or as an exaggeratedly intense or distorted pain response to typically nonpainful touch. While there is currently no cure, treatments for the pain associated with peripheral neuropathy include prescription medications and other approaches such as transcutaneous electrical nerve stimulation, braces, and behavioral therapies. FDA is interested in the perspectives of patients with peripheral neuropathy on specifically: (1) The impact of neuropathic pain associated with peripheral neuropathy and (2) treatment approaches for the neuropathic pain associated with peripheral neuropathy.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief initial patient panel discussion will begin the dialogue. This will be followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through written comments, which can be submitted to the public docket (see **ADDRESSES**).

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

1. How would you describe your neuropathic pain associated with peripheral neuropathy? What terms would you use to describe the most bothersome aspects of pain? (Examples may include stabbing sensations, electric shocks, burning or tingling, etc.)

2. 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 your neuropathic pain? (Examples of activities may include sleeping through the night, daily hygiene, participation in sports or social activities, intimacy with a spouse or partner, etc.)

3. How do your neuropathic pain and its negative impacts affect your daily life on the best days? On the worst days?

4. How has your neuropathic pain changed over time?

5. What worries you most about your condition?

#### Topic 2: Patients' Perspectives on Current Approaches to Treatment

1. What are you currently doing to help treat your neuropathic pain associated with peripheral neuropathy? (Examples may include prescription medicines, over-the-counter products, and other therapies including non-drug therapies). How has your treatment regimen changed over time, and why?

2. How well does your current treatment regimen control your neuropathic pain?

a. How well have these treatments worked for you as your condition has changed over time?

b. Would you define your condition today as being well managed?

3. What are the most significant downsides to your current treatments, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, going to the hospital or clinic for treatment, time devoted to treatment, restrictions on driving, etc.)

4. Assuming there is no complete cure for your neuropathic pain, what specific things would you look for in an ideal treatment for your neuropathic pain? What would you consider to be a meaningful improvement in your condition (for example, specific symptom improvements or functional improvements) that a treatment could provide?

5. If you had the opportunity to consider participating in a clinical trial studying experimental treatments for neuropathic pain, what things would you consider when deciding whether or not to participate? (Examples may include how severe your neuropathic pain is, how well current treatments are working for you, your concern about risks, etc.)

#### B. Meeting Attendance and Participation

If you wish to attend this meeting, visit <https://peripheralneuropathypfdd.eventbrite.com>. Please register by June 3, 2016. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If

you need special accommodations because of a disability, please contact Meghana Chalasani (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients also must send to *Patient Focused@fda.hhs.gov* a brief summary of responses to the topic questions by May 27, 2016. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

*Docket Comments:* Regardless of whether you attend the public meeting, you can submit electronic or written responses to the questions pertaining to topics 1 and 2 to the public docket (see **ADDRESSES**) by August 10, 2016. 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>.

*Transcripts:* As soon as a transcript is available, FDA will post it at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm470608.htm>.

Dated: April 13, 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-1097]

#### AbbVie Inc.; Withdrawal of Approval of New Drug Applications for ADVICOR and SIMCOR

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of the new drug applications (NDAs) for ADVICOR (niacin extended-release (ER) and lovastatin) tablets and SIMCOR (niacin ER and simvastatin) tablets. The holder of these two applications, AbbVie Inc.,

has requested that FDA withdraw approval of the applications and has waived its opportunity for a hearing. The Agency has also determined that ADVICOR and SIMCOR were withdrawn from sale for reasons of safety and effectiveness, and FDA will not accept or approve abbreviated new drug applications (ANDAs) that reference ADVICOR or SIMCOR.

**DATES:** The effective date is April 18, 2016.

**ADDRESSES:** For access to the docket to read background documents, 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 (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Jay Sitlani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6282, Silver Spring, MD 20993-0002, 301-796-5202.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA approved NDA 021249 for ADVICOR on December 17, 2001. ADVICOR is a fixed-combination drug product containing niacin ER and lovastatin in tablet form. The drug is approved in four strengths of niacin ER and lovastatin, respectively: (1) 500 milligrams (mg), 20 mg; (2) 750 mg, 20 mg; (3) 1 gram (g), 20 mg; and (4) 1 g, 40 mg. The approved indication reads as follows:

ADVICOR is indicated for the treatment of primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Frederickson Types IIa and IIb; Table 6) in:

- Patients treated with lovastatin who require further TG-lowering or HDL-raising who may benefit from having niacin added to their regimen
- Patients treated with niacin who require further LDL-lowering who may benefit from having lovastatin added to their regimen

The indication was revised subsequent to the initial approval and currently states that ADVICOR is approved for the treatment of hypercholesterolemia when treatment with both Niaspan and lovastatin is appropriate.

FDA approved NDA 022078 for SIMCOR on February 15, 2008. SIMCOR is a fixed-combination drug product containing niacin ER and simvastatin in tablet form. The drug is approved in five

strengths of niacin ER and simvastatin, respectively: (1) 500 mg, 20 mg; (2) 500 mg, 40 mg; (3) 750 mg, 20 mg; (4) 1 g, 20 mg; and (5) 1 g, 40 mg. SIMCOR is approved for the following indications:

- To reduce TC, LDL-C, apolipoprotein B, non-HDL-C, triglycerides (TG), or to increase HDL-C in patients with primary hypercholesterolemia and mixed dyslipidemia when treatment with simvastatin monotherapy or niacin ER monotherapy is considered inadequate
- To reduce TG in patients with hypertriglyceridemia when treatment with simvastatin monotherapy or niacin ER monotherapy is considered inadequate

The labeling includes the following Limitation of Use in the Indications and Usage section of the labeling:

- No incremental benefit of SIMCOR on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin monotherapy and niacin monotherapy has been established.

**II. Withdrawal Under Section 505(e) of the FD&C Act**

Based on the collective evidence from several large cardiovascular outcome trials (Refs. 1-3.), the Agency has concluded that the totality of the scientific evidence no longer supports the conclusion that a drug-induced reduction in triglyceride levels and/or increase in HDL-cholesterol levels in statin-treated patients results in a reduction in the risk of cardiovascular events. Consistent with this conclusion, FDA has determined that the benefits of ADVICOR and SIMCOR no longer outweigh the risks, and approval should be withdrawn.

FDA requested that AbbVie Inc. voluntarily discontinue marketing of ADVICOR and SIMCOR, and AbbVie Inc. agreed to do so. AbbVie Inc. also has requested in writing that FDA withdraw approval of NDA 021249 and NDA 022078 and waived its opportunity for a hearing.

Therefore, under section 505(e) of the FD&C Act and under authority delegated to the Director of the Center for Drug Evaluation and Research by the Commissioner of Food and Drugs, approval of ADVICOR and SIMCOR is withdrawn. Introduction or delivery for introduction of these products without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

The Agency is required to publish a list of all approved drugs (see section 505(j)(7) of the FD&C Act (21 U.S.C.

355(j)(7)). 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 314.161 and 314.162(a)(2)). For the reasons summarized in this document, the Agency has determined that ADVICOR and SIMCOR were voluntarily withdrawn from sale for reasons of safety or effectiveness. FDA will remove NDA 021249 for ADVICOR and NDA 022078 for SIMCOR from the list of products published in the Orange Book and will not accept or approve ANDAs that reference either drug product.

**III. References**

The following references are on display in the Division of Dockets Management (see **ADDRESSES**), and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. The ACCORD Study Group, "Effects of Combination Lipid Therapy in Type 2 Diabetes Mellitus," *New England Journal of Medicine*, vol. 362, pp. 1563-1574, 2010 (<http://www.nejm.org/doi/pdf/10.1056/NEJMoa1001282>).
2. The AIM-HIGH Investigators, "Niacin in Patients with Low HDL Cholesterol Levels Receiving Intensive Statin Therapy," *New England Journal of Medicine*, vol. 365, pp. 2255-2267, 2011 (<http://www.nejm.org/doi/pdf/10.1056/NEJMoa1107579>).
3. The HPS2-THRIVE Collaborative Group, "Effects of Extended-Release Niacin with Laropiprant in High-Risk Patients," *New England Journal of Medicine*, vol. 371(3), pp. 203-212, 2014 (<http://www.nejm.org/doi/pdf/10.1056/NEJMoa1300955>).

Dated: April 13, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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