and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5197, Silver Spring, MD 20993, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act.''

Section 503B, added to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by the Drug Quality and Security Act in 2013, created a new category of compounders called *outsourcing facilities.* Section 503B describes the conditions that must be satisfied for human drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility to qualify for exemptions from three sections of the FD&C Act:

- Section 502(f)(1) (concerning labeling requirements);
- Section 505 (concerning drug approval requirements); and
- Section 582 (concerning Drug Supply Chain Security Act requirements).

Section 503B(d)(4) of the FD&C Act defines an outsourcing facility as a facility at one geographic location or address that: (1) Is engaged in the compounding of sterile drugs; (2) has elected to register as an outsourcing facility; and (3) complies with all of the requirements of this section. In addition, an outsourcing facility is not required to be a licensed pharmacy, and it may or may not obtain prescriptions for identified individual patients. Because drugs compounded by outsourcing facilities are not exempt from section 501(a)(2)(B) of the FD&C Act, outsourcing facilities are subject to current good manufacturing practice (CGMP) requirements.

FDA has received questions from outsourcing facilities and other stakeholders about the meaning of the term ''facility at one geographic location or address,'' such as whether multiple suites used for compounding human drugs at a single street address constitute one or multiple facilities, or whether a single location where human drugs are compounded can be subdivided into separate operations compounding under different standards. FDA is issuing this draft guidance to answer these questions.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the meaning of the term ''facility at one geographic location or address'' under section 503B of the FD&C Act. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: April 12, 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–1127]

AbbVie Inc. et al; Withdrawal of Approval of Indications Related to the Coadministration With Statins in Applications for Niacin Extended-Release Tablets and Fenofibric Acid Delayed-Release Capsules

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of the indications related to the coadministration with a statin for niacin extended-release (ER) tablets and fenofibric acid delayed-release (DR) capsules. Affected applications include one new drug application (NDA) and seven abbreviated new drug applications (ANDAs) for niacin ER tablets, and one NDA and three ANDAs for fenofibric acid DR capsules. The holders of these applications have requested that FDA withdraw approval of the indications and have waived their opportunities for a hearing.

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

A. Applications for Niacin ER Tablets

FDA first approved NDA 020381 for Niaspan (niacin extended-release) tablets for several indications on July 28, 1997. On March 26, 2009, FDA approved a revised indication that read as follows:

- Niaspan in combination with simvastatin or lovastatin is indicated for the treatment of primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Fredrickson Types IIa and IIb) when treatment with Niaspan, simvastatin, or lovastatin monotherapy is considered inadequate.

In addition, the following Limitation of Use was added to the Indications and Usage section of the labeling:

- No incremental benefit of Niaspan coadministered with simvastatin or lovastatin on cardiovascular morbidity and mortality over and above that demonstrated for niacin, simvastatin, or lovastatin monotherapy has been established. Niaspan has not been studied in Fredrickson Type I and III dyslipidemias.

This indication was revised between March 26, 2009, and April 27, 2015, at which time it was removed from the approved labeling. The Limitation of Use currently reads:

- Addition of Niaspan did not reduce cardiovascular morbidity or mortality among patients treated with simvastatin in a large, randomized controlled trial (AIM–HIGH).

There are seven approved ANDAs that cited Niaspan as the reference listed drug (RLD) and that are approved for the same indications as Niaspan (see table 1).

TABLE 1—AFFECTED NIACIN PRODUCTS

Application No.	Drug	Application holder
NDA 020381	Niaspan (niacin extended-release) tablets	AbbVie.
ANDA 076250	Niacin extended-release tablets	Barr.
ANDA 076378	Niacin extended-release tablets	Barr.
ANDA 090446	Niacin extended-release tablets	Lupin Ltd.
ANDA 090860	Niacin extended-release tablets	Lupin Ltd.
ANDA 090892	Niacin extended-release tablets	Lupin Ltd.
ANDA 200484	Niacin extended-release tablets	Sun Pharma Global.
ANDA 201273	Niacin extended-release tablets	Sun Pharma Global.

B. Applications for Fenofibric Acid DR Capsules

FDA approved NDA 022224 for Trilipix (fenofibric acid) DR capsules on December 15, 2008, for several indications, including the following:

- Trilipix is indicated as an adjunct to diet in combination with a statin to reduce TG and increase HDL–C in patients with mixed dyslipidemia and CHD (coronary heart disease) or a CHD risk equivalent who are on optimal statin therapy to achieve their LDL–C goal.

CHD risk equivalents comprise:

- Other clinical forms of atherosclerotic disease (peripheral arterial disease, abdominal aortic aneurysm, and symptomatic carotid artery disease);
- Diabetes; and
- Multiple risk factors that confer a 10-year risk for CHD >20 percent.

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

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

Both this indication and the Limitation of Use were removed from the labeling on April 27, 2015.

There are three approved ANDAs that cited Trilipix as the RLD and that are approved for the same indications as Trilipix (see table 2).

TABLE 2—AFFECTED FENOFIBRIC ACID PRODUCTS

Application No.	Drug	Application holder
NDA 022224	Trilipix (fenofibric acid) delayed-release capsules	AbbVie.
ANDA 201573	Fenofibric acid delayed-release capsules	Anchen Pharmaceuticals.
ANDA 200750	Fenofibric acid delayed-release capsules	Lupin Ltd.
ANDA 200913	Fenofibric acid delayed-release capsules	Mylan Pharmaceuticals Inc.

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 niacin ER tablets and fenofibric acid DR capsules for coadministration with statins no longer outweigh the risks, and the approvals for this indication should be withdrawn.

FDA requested that the application holders voluntarily discontinue marketing of niacin ER tablets and fenofibric acid DR capsules for these indications. The NDA and ANDA holders identified above have requested in writing that FDA withdraw approval of these indications and waived their 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, the approvals of the indications related to coadministration with statins for the applications listed in tables 1 and 2 are withdrawn. Introduction or delivery for introduction of these products with these indications in interstate commerce 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)).

III. References

The following references are on display in the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 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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