Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's Web site at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA's Web site and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on December 23, 2016 (81 FR 94394). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's Web site.

II. Drug Products for Which New Draft Product-Specific Guidances are Available

FDA is announcing the availability of a new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Acetylcysteine
Amphetamine
Aprepitant
Azelastine hydrochloride
Bisacodyl; polyethylene glycol 3350; potassium chloride; sodium bicarbonate; sodium chloride
Carbidopa; levodopa
Chlordiazepoxide hydrochloride; Clidinium bromide
Clonazepam
Edoxaban tosylate
Gentamicin sulfate
Hydrocortisone
Hydrocortisone butyrate
Linagliptin; Metformin hydrochloride
Lorcaserin hydrochloride
Methylnaltrexone bromide
Nitroglycerin
Nystatin; Triamcinolone acetonide (multiple reference listed drugs)
Oxymetazoline hydrochloride; Tetracaine hydrochloride
Sofosbuvir; Velpatasvir
Venetoclax

III. Drug Products for Which Revised Draft Product-Specific Guidances are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Acamprosate calcium
Apixaban
Bexarotene
Calcium acetate (multiple reference listed drugs)
Deferiprone
Dolutegravir sodium
Emtricitabine; Tenofovir disoproxil fumarate
Fingolimod
Lanthanum carbonate
Nevirapine
Phenytoin (multiple reference listed drugs)
Propafenone hydrochloride
Trospium chloride (multiple reference listed drugs)

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Electronic Access

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

Dated: May 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–09961 Filed 5–16–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–2364]

Determination That CALCIJEX (Calcitriol) Injectable, 1 Microgram/Milliliter and 2 Micrograms/Milliliter, 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 or Agency) has determined that the drug product listed in this document was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363.

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 approved 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 generally known as the ''Orange Book.'' Under FDA regulations, a drug is 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).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug product listed in the table in this document is no longer being marketed.

Application No.	Drug name	Active ingredient	Strength(s)	Dosage form/route	Applicant
NDA 018874	CALCIJEX	Calcitriol	1 microgram (mcg)/milliliter (mL); 2 mcg/mL	Injectable; Injection	AbbVie, Inc.

FDA has reviewed its records and, under § 314.161, has determined that the drug product listed in this document was not withdrawn from sale for reasons of safety or effectiveness.[1] Accordingly, the Agency will continue to list the drug product listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDA listed in this document are unaffected by the discontinued marketing of the products subject to that NDA. Additional ANDAs that refer to this product may also be approved by the Agency if they comply with relevant legal and regulatory requirements. 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.

This is not a significant regulatory action subject to Executive Order 12866 and does not impose any additional burden on regulated entities.

Dated: May 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–09960 Filed 5–16–17; 8:45 am]

BILLING CODE 4164–01–P

[1] We have also determined that the previous CALCIJEX formulation originally approved on September 25, 1986, and superseded by the currently approved formulation was not withdrawn for reasons of safety or effectiveness.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Dates and Times: Wednesday, June 21, 2017: 9:00 a.m.–5:30 p.m.

Thursday, June 22, 2017: 8:30 a.m.–3:15 p.m.

Place: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW., Room 705A, Washington, DC 20201, (202) 690–7100.

Status: Open.

Purpose: At the June 21–22, 2017 meeting, the Committee will hear presentations, hold discussions on several health data policy topics, and receive updates from HHS, the Office of the National Coordinator for Health IT, the CDC National Center for Health Statistics, the National Library of Medicine, and Centers for Medicare and Medicaid Services. On the first day, the Committee will focus on two items anticipated for action: A recommendation letter that addresses the Health Plan Identifier in follow up to the May 3, 2017 HPID Hearing, and follow up on the NCVHS June 2016 Hearing on claims-based databases for policy development and evaluation. The Committee will review status reports on various NCVHS products; an upcoming hearing on the next generation of vital statistics; and the Predictability Roadmap under development by the Standards Subcommittee. Significant time will be devoted to discussion and formulation of two new complex long-term project topics—an environmental scan of terminology & vocabulary development, maintenance and dissemination processes on the first day; on the second day, building on past work, exploration of a range of challenges beyond HIPAA and the range of policy options that may be available to the Department related to privacy, security and access measures to protect individually identifiable health information in an environment of electronic networking and multiple uses of data. In addition, the Committee will continue to focus on planning efforts and follow-up items on actions from the previous day.

The times and topics are subject to change. Please refer to the posted agenda for any updates.

Contact Person for More Information: Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, telephone (301) 458–4715. Summaries of meetings and a roster of Committee members are available on the home page of the NCVHS Web site: *http://www.ncvhs.hhs.gov/,* where further information including an agenda and instructions to access the audio broadcast of the meetings will also be posted. Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (770) 488–3210 as soon as possible.

Dated: May 9, 2017.

Laina Bush,

Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2017–09982 Filed 5–16–17; 8:45 am]

BILLING CODE 4151–05–P