- Double spaced.
- Page margin size: One inch.
- Number all narrative pages; not to exceed the maximum number of pages.
- Include a table of contents.
- Application should be submitted through Grantsolutions at *www.grantsolutions.gov*.

The narrative should address activities to be conducted over the entire project period and must include the following items in the order listed:

i. Plan.

ii. Methods.

iii. Objectives.

iv. Timeline.

v. Staff.

vi. Understanding.

vii. Need.

viii. Evaluation and Performance Measures.

The budget and budget justification will be included as a separate attachment, not to be counted in the narrative page limit. Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:

- Curriculum Vitae, Resumes, Organizational Charts, and Letters of Support. Additional information submitted via GrantSolutions.gov should be uploaded in a PDF file format, and should be named as appropriate, such as publications, reports, etc.
- No more than 15 attachments should be uploaded per application.

G. Work Plan.

H. Grantees will be required to access the non-competing application kit in GrantSolutions.gov to submit all materials for this application.

IV. Application Review Information

Applications will be objectively reviewed by Federal staff utilizing the evaluation criteria listed above in Section II.

V. Agency Contact

For further information or comments regarding this program expansion supplement, contact Ophelia M. McLain, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Intellectual and Developmental Disabilities, Office of Innovation, One Massachusetts Avenue NW., Washington, DC 20001; telephone (202) 690–7025; fax (202) 357–3560; email *Ophelia.McLain@acl.hhs.gov*.

Dated: April 8, 2014.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2014–08195 Filed 4–10–14; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–P–1515]

Determination That ZOVIRAX (Acyclovir Sodium) Injection, Equivalent to 250 Milligrams Base/Vial, 500 Milligrams Base/Vial, and 1 Gram Base/Vial, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 ZOVIRAX (acyclovir sodium) Injection, equivalent to (EQ) 250 milligrams (mg) base/vial, 500 mg base/vial, and 1gram (g) base/vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1 g base/vial, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Darren Eicken, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 240–402–0978.

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.

ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1g base/vial, is the subject of NDA 18–603, held by GlaxoSmithKline and initially approved on October 22, 1982. ZOVIRAX (acyclovir sodium) is indicated for the treatment of herpes and varicella-zoster (shingles) in immunocompromised patients.

In a letter dated June 20, 2005, GlaxoSmithKline notified FDA that ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1g base/vial, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated November 15, 2013 (Docket No. FDA–2013–P–1515), under 21 CFR 10.30, requesting that the Agency determine whether ZOVIRAX (acyclovir sodium) Injection, EQ 1 g base/vial, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 250 mg and 500 mg strengths, those strengths have also been discontinued. On our own initiative, we have also determined whether those strengths were withdrawn for safety or effectiveness reasons.

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 ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1g base/vial, was

not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1 g base/vial, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1g base/vial, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1g base/vial, 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 ZOVIRAX (acyclovir sodium) Injection, EQ 250 mg base/vial, 500 mg base/vial, and 1g base/vial, 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: April 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08148 Filed 4–10–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Nonprescription Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Nonprescription Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 2, 2014, from 8 a.m. to 4:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD. The hotel phone number is 301–977–8900.

Contact Person: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *NDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss data submitted by MSD Consumer Care, Inc., to support new drug application (NDA) 204804, for over-the-counter (OTC) marketing of montelukast 10 milligram (mg) tablets (proposed trade name SINGULAIR Allergy). The proposed OTC use is ''temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: Nasal congestion, runny nose, itchy, watery eyes, sneezing, itching of the nose.'' The applicant proposes to label the product for OTC use in adults 18 years and older. Efficacy and safety data, as well as results of consumer studies, will be discussed. The committee will be asked to consider whether the data support an acceptable risk/benefit profile for the nonprescription use of montelukast tablets by OTC consumers.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 25, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 17, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 18, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kalyani Bhatt at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 8, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–08154 Filed 4–10–14; 8:45 am]

BILLING CODE 4160–01–P