• 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.

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Sodium) Injection, Equivalent to 250 Milligrams Base/Vial, 500 Milligrams Base/Vial, and 1 Gram Base/Vial, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 1 gram (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.


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
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.


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) montelukast sodium (acyclovir sodium) injection, for nonprescription use of montelukast sodium (acyclovir sodium) injection, 250 mg base/vial, 500 mg base/vial, and 1 g base/vial, from sale. The Agency 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.

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