DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-867

Sandoz, Inc.
Attention: Enna Krivitsky
Director, Regulatory Affairs
227-15 North Conduit Avenue
Laurelton, NY 11413

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated October 3, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Albuterol Sulfate and Ipratropium Bromide Inhalation Solution, 3 mg(0.083%) and 0.5 mg(0.017%), respectively, packaged in 3 mL unit-dose vials.

Reference is also made to your amendments dated July 21, 2005, and April 28, June 20, July 18, August 4, and August 28, 2006. We also acknowledge receipt of your correspondence dated November 7, 2003, March 15, 2004, and November 22, and December 29, 2005, addressing the patent issues associated with this ANDA.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Albuterol Sulfate and Ipratropium Bromide Inhalation Solution, 3 mg/0.5 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), DuoNeb Inhalation Solution, 3 mg/0.5 mg, of Dey L.P. (Dey).

The RLD upon which you have based your ANDA, Dey's DuoNeb Inhalation Solution, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations

(the "Orange Book"), U.S. Patent No. 6,632,842 (the '842 patent) is scheduled to expire on December 28, 2021.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '842 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Albuterol Sulfate and Ipratropium Bromide Inhalation Solution under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless action was brought against Sandoz, Inc. (Sandoz, formerly Eon Labs, Inc.) for infringement of the '842 patent that was the subject of the paragraph IV certification. You have notified the agency that Sandoz complied with the requirements of section 505(j)(2)(B) of the Act and, within the statutory 45-day period, litigation was initiated against Sandoz for infringement of the '842 patent in the United States District Court for the Central District of California, Southern Division [DEY, L.P., v. EON LABS, Inc., Civil Action No. SACV 04-00243]. You have also notified the agency that the court order dated December 22, 2005, provided for the termination of the statutory 30-month stay of approval of your ANDA. Your ANDA, therefore, is eligible for approval.

With respect to 180-day generic drug exclusivity, we note that Sandoz was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '842 patent. Therefore, with this approval, the agency has determined that Sandoz is eligible for 180 days of generic drug exclusivity for Albuterol Sulfate and Ipratropium Bromide Inhalation Solution. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv).[1] Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

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[1] Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

Postmarketing reporting requirements for this ANDA application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert L. West
12/21/2006 02:13:11 PM
for Gary Buehler