DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-104

Barr Laboratories, Inc.
Attention: Nicholas Tantillo
Senior Director, Regulatory Affairs
225 Summit Avenue
Montvale, NJ 07645

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 28, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Triamcinolone Acetonide Nasal Spray, 0.055 mg (55 micrograms)/spray, packaged in 120 metered spray containers.

Reference is also made to your amendments dated October 5, 2006; February 21, May 24, July 12, 16, and 26, August 13 and 31, and October 12, 2007; February 15, March 7, June 27, July 14, August 18 (two submissions), October 7 and 22, 2008; and March 11, May 12, and July 8, 2009. In addition, we acknowledge receipt of your correspondence dated April 19, and May 9, 2006; October 20, 2008; and March 13, 2009, addressing 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 Triamcinolone Acetonide Nasal Spray, 0.055 mg (55 micrograms)/spray, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Nasacort AQ Nasal Spray, 0.055 mg (55 micrograms)/ spray of Sanofi-Aventis US LLC (Sanofi).

The RLD upon which you have based your ANDA, Sanofi's Nasacort AQ Nasal Spray, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 5,976,573 (the '573 patent) and 6,143,329 (the '329 patent) are both scheduled to expire on July 3, 2016.

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is

invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Triamcinolone Acetonide Nasal Spray, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against Barr Laboratories, Inc. (Barr) for infringement of one or more of the patents that were the subjects of the paragraph IV certifications. You have notified the agency that Barr complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Barr for infringement of the '573 and '329 patents in the United States District Court for the District of Delaware [Aventis Pharmaceuticals Inc. and Sanofi-Aventis US LLC v. Barr Laboratories, Inc., Civil Action No. 06-286]. Subsequently, you notified the agency that Barr and the plaintiffs agreed to dismiss litigation with respect to patent infringement.

With respect to the RLD's new patient population exclusivity, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act that this marketing exclusivity does not correspond to any proposed indication for which you are seeking approval under your ANDA.

With respect to 180-day generic drug exclusivity, we note that Barr was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '573 and '329 patents. Therefore, with this approval, Barr may be eligible for 180 days of generic drug exclusivity for Triamcinolone Acetonide Nasal Spray, 0.055 mg (55 micrograms)/spray. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, begins to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins. The agency notes that Barr failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the Act. However, the agency is not making a formal determination at this time of Barr's eligibility for 180-day generic drug exclusivity. It will do so only if another applicant becomes eligible for approval within 180 days after Barr begins commercial marketing of Triamcinolone Acetonide Nasal Spray, 0.055 mg (55 micrograms)/spray.

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.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA 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(s) 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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as ***"Miscellaneous Correspondence - SPL for Approved ANDA 78-104".***

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
07/30/2009
Deputy Director, for Gary Buehler