DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 091161

APPROVAL

Apotex Corp.
U.S. Agent for Apotex Inc.
2400 North Commerce Parkway, Suite 400
Weston, FL 33326
Attention: Kiran Krishnan
Vice President, Regulatory Affairs

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Mometasone Furoate Nasal Spray, 50 mcg.

Reference is also made to the complete response letter issued by this office on December 3, 2015, and to your amendments dated December 18, 2015; and January 14, February 22, and March 17, 2016.

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 Office of Bioequivalence has determined your Mometasone Furoate Nasal Spray, 50 mcg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Nasonex Nasal Spray of Merck Sharp & Dohme Corp. (Merck).

The RLD upon which you have based your ANDA, Merck's Nasonex Nasal Spray, 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. 6,127,353 (the '353 patent), is scheduled to expire (with pediatric exclusivity added) on April 3, 2018.

Your ANDA contains a paragraph IV certification to the '353 patent under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Mometasone Furoate Nasal Spray, 50 mcg, under this ANDA. You have notified the agency that Apotex Inc. (Apotex) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that litigation was initiated against Apotex for infringement of the '353 patent within the statutory 45-day period in the United States District Court for the District of New Jersey [Merck Sharp & Dohme Corp. formerly known as Schering Corporation vs. Apotex Inc. and Apotex Corp., Civil Action No. 12-1516]. You have also informed the Agency that on June 15, 2012 the district court determined

that Apotex's product does not infringe the '353 patent. This judgment was affirmed by the United States Court of Appeals for the Federal Circuit on June 10, 2013.

With respect to 180-day generic drug exclusivity, we note that Apotex was the first ANDA applicant for Mometasone Furoate Nasal Spray, 50 mcg, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Apotex may be eligible for 180 days of generic drug exclusivity for Mometasone Furoate Nasal Spray, 50 mcg. This exclusivity, which is provided for under 505(j)(5)(B)(iv) of the FD&C Act, would begin to run from the date of the commercial marketing identified in section 505(j)((5)(B)(iv). The agency notes that Apotex failed to obtain tentative approval of this ANDA within 30 months after the date of which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the FD&C Act (forfeiture of exclusivity for failure to obtain tentative approval). The agency also notes that Apotex may have forfeited its eligibility for 180-day exclusivity under the "failure to market" provision (see section 505(j)(5)(D)(i)(I) of the FD&C Act). The agency is not making a formal determination at this time of Apotex's eligibility for 180-day generic drug exclusivity, however. It will do so only if a subsequent paragraph IV applicant becomes eligible for full approval (a) within 180 days after Apotex begins commercial marketing of Mometasone Furoate Nasal Spray, 50 mcg, or (b) at any time prior to the expiration of the '353 patent if Apotex has not begun commercial marketing. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

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

Please 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 FD&C Act.

Post-marketing 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
Office of Prescription Drug Promotion
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 Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

You have been requested to provide information after the ANDA has been approved. Any information submitted to meet the conditions requested in this letter is considered a "Post Approval Commitment Response." To alert the Office of Generic Drug staff to the fact that you are providing post approval commitment information, please designate your submission in your cover letter as "POST APPROVAL COMMITMENT RESPONSE."

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

Carol A. Holquist -S

Digitally signed by Carol A. Holquist -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300052464, cn=Carol A. Holquist -S
Date: 2016.03.22 08:21:22 -04'00'

Carol A. Holquist, RPh
Acting Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research