DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 203592

ANDA APPROVAL

IBA Molecular North America, Inc.
21000 Atlantic Blvd., Suite 730
Dulles, VA 20166
Attention: David W. Pellicciarini
Vice President, RA/QA/EHS

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 12, 2011, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), for Sodium Fluoride F18 Injection USP, 10 mCi/mL - 200 mCi/mL at End of Synthesis (EOS).

Reference is also made to your amendments dated January 10, May 22, and August 8, 2012; July 10, 2013; February 21 and April 22, 2014.

We note that the reference listed drug product (RLD) upon which you have based this ANDA, Sodium Fluoride F18 Injection USP, 10 mCi/mL -200 mCi/mL at EOS of the National Cancer Institute (NCI), National Institutes of Health (NIH), is no longer being marketed in the United States, and has been moved to the Discontinued section of the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book". We refer to the Federal Register Notice dated June 24, 2011 (Volume 76, No. 122) in which the agency announced its determination that NCI's Sodium Fluoride F18 Injection USP, 10 mCi/mL - 200 mCi/mL at EOS, was not withdrawn from sale for reasons of safety or effectiveness. This determination allows the agency to approve ANDAs for the discontinued drug product.

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 Sodium Fluoride F18 Injection USP, 10 mCi/mL - 200 mCi/mL at EOS to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug product (RLD), Sodium Fluoride F18 Injection USP, 10 mCi/mL - 200 mCi/mL at EOS, of the National Cancer Institute, National Institutes of Health.

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.

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
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.

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,

William P. Rickman -S

Digitally signed by William P. Rickman -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300043242, cn=William P. Rickman -S
Date: 2015.08.18 15:16:56 -04'00'

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