# FDA FAX

ANDA 202675

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TO: Aurolife Pharma LLC

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ATTN: Blessy Johns

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FROM: Erin Lee

PROJECT MANAGER: erin.lee@fda.hhs.gov

Dear Madam:

This facsimile is in reference to your abbreviated new drug application dated January 12, 2011, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Glycopyrrolate Tablets, 1 mg and 2 mg.

**Pages (including cover): ____**

**SPECIAL INSTRUCTIONS:**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 202675

Aurolife Pharma LLC
Attention: Blessy Johns
Senior Manager, Regulatory Affairs
2400 Route 130 North
Dayton, NJ 08810

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated January 12, 2011, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Glycopyrrolate Tablets USP, 1 mg and 2 mg.

Reference is also made to your amendments dated March 2, April 13, April 28, and May 26, 2011; March 16, May 7, September 7, and September 19, 2012; and February 12, 2013.

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, your Glycopyrrolate Tablets USP, 1 mg, is approved, effective on the date of this letter. However, because of the exclusivity issue explained below, we are unable to grant final approval at this time to your Glycopyrrolate Tablets USP, 2 mg. Your Glycopyrrolate Tablets USP, 2 mg, is tentatively approved.

The RLD upon which you have based your ANDA, Robinul Tablets, 1 mg and 2 mg, of Shionogi Inc. (Shionogi), 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. 7,091,236 (the '236 patent), is scheduled to expire on April 24, 2024.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '236 patent is invalid, unenforceable, or will not be infringed by your

manufacture, use, or sale of Glycopyrrolate Tablets USP, 1 mg and 2 mg, under this ANDA. You have notified the agency that Aurolife Pharma LLC (Aurolife) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Aurolife within the statutory 45-day period.

## I. Approval of Glycopyrrolate Tablets USP, 1 mg.

The Division of Bioequivalence has determined your Glycopyrrolate Tablets USP, 1 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Robinul Tablets, 1 mg, of Shionogi Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

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.

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 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 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.

**II. Tentative Approval of Glycopyrrolate Tablets USP, 2 mg.**

We are unable at this time to grant final approval of your Glycopyrrolate Tablets USP, 2 mg. Prior to the receipt of your ANDA insofar as this strength, another ANDA applicant submitted an ANDA for Glycopyrrolate Tablets USP, 2 mg, containing a paragraph IV certification. This other ANDA, therefore, is eligible for 180-day generic drug exclusivity under section 505(j)(5)(B)(iv) for Glycopyrrolate Tablets USP, 2 mg. Your ANDA insofar as the 2 mg strength will be eligible for final approval upon the expiration of the other applicant's 180-day exclusivity, or that exclusivity is otherwise resolved.

Our decision to tentatively approve the 2 mg strength is based upon information currently available to the agency, i.e., data in your ANDA and the status of current good manufacturing practice (cGMP) of the facilities used in the manufacture and testing of the drug product. This decision is subject to change on the basis of new information that may come to our attention.

To reactivate your ANDA for Glycopyrrolate Tablets USP, 2 mg, prior to final approval, please submit a "Final Approval Request Amendment to Original #2" 90 days prior to the date you believe that this product will be eligible for final approval. Your amendment must provide a summary of the legal basis upon which you believe the ANDA should be approved, as well as:

1. updated information related to final-printed labeling or chemistry, manufacturing and controls data, or any other change in the conditions outlined in this ANDA, or
2. a statement that no such changes have been made to the ANDA since the date of tentative approval.

Any changes in the conditions outlined in this ANDA and the status of the manufacturing and testing facilities' compliance with current good manufacturing practice (cGMP) are subject to Agency review before final approval of your Glycopyrrolate Tablets USP, 2 mg, will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt.

In addition to the amendment requested above, the agency may request at any time prior to the final date of approval that you submit an additional amendment containing the requested information. Failure to submit either amendment may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

Your Glycopyrrolate Tablets USP, 2 mg, may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of a drug before the effective final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, the 2 mg strength product will not be listed in the "Orange Book."

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 dose form (FDFs) or active pharmaceutical ingredient (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.

In addition, we note that GDUFA requires that certain non-manufacturing sites and organizations listed in generic drug submissions comply with the self-identification requirement. The failure of any facility, site, or organization to comply with its obligation to self-identify and/or to pay fees when due may raise significant concerns about that site or organization and is a factor that may increase the likelihood of a site inspection prior to approval. FDA does not expect to give priority to completion of inspections that are required simply because facilities, sites, or organizations fail to comply with the law requiring self-identification or fee payment.

Additionally, we note that the failure of any facility referenced in the application to self-identify and pay applicable fees means that FDA will not consider the GDUFA application review goal dates to apply to that application.

For further information on the status of this ANDA, or prior to submitting additional supplements, please contact Erin Lee, Pharm.D., Project Manager, at erin.lee@fda.hhs.gov

Sincerely yours,

*(See appended electronic signature page)*

Kathleen Uhl, M.D.
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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

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/s/

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ROBERT L WEST
04/15/2013
Deputy Director, Office of Generic Drugs, for
Kathleen Uhl, M.D.