DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 074978/S-030

Actavis Mid Atlantic LLC
Attn: Elizabeth Trowbridge
200 Elmora Avenue
Elizabeth, NJ 07207

Dear Madam:

This is in reference to your supplemental new drug application dated September 30, 2008, submitted pursuant to 21 CFR 314.70 (c) (Supplement-Changes Being Effected in 30 days), regarding your abbreviated new drug application for Ibuprofen Oral Suspension USP, 100 mg/5 mL.

This supplemental new drug application provides for revised labels and labeling to include the new manufacturing facility, Actavis Mid Atlantic LLC in Lincolnton, North Carolina.

We have completed the review of this supplemental application and it is approved. However, please make the following revision at the next time of printing:

GENERAL COMMENT:

Please revise the storage temperature to read "Store at 20ºC to 25ºC (68ºF to 77 ºF). [See USP Controlled Room Temperature.]"

The above revisions can be reported in your next annual report provided they are described in full.

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research

Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The materials submitted are being retained in our files.

Sincerely yours,

{See appended electronic signature page}

Wm Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-74978	SUPPL-30	ACTAVIS MID ATLANTIC LLC	IBUPROFEN

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

/s/

KOUNG U LEE
06/03/2010
For Wm Peter Rickman