DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDAs 071745
071994
071995

CONSOLIDATION APPROVAL

RECEIVED
SEP 8 2016
Teva Pharmaceuticals USA
Regulatory Affairs Department

Teva Pharmaceuticals USA, Inc.
425 Privet Road
Horsham, PA 19044
Attention: Barinder Sandhu

Dear Barinder Sandhu,

This is in reference to the correspondences dated April 20, 2016 regarding your Abbreviated New Drug Applications (ANDAs) submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act for Prazosin Hydrochloride Capsules USP, 1 mg (ANDA 071994), Prazosin Hydrochloride Capsules USP, 2 mg (ANDA 071995), and Prazosin Hydrochloride Capsules USP, 5 mg (ANDA 071745).

These correspondences request the following change:

> Consolidation of multiple approved ANDAs into a single application in compliance with the CDER guidance entitled: "Variations in Drug Products that may be included in a Single ANDA."

You have requested consolidation of ANDAs 071994 and 071995 into **ANDA 071745**. We have completed the review of these correspondences and your request is approved.

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

ANDAs 071745
071994
071995

If you have any questions, contact Kathleen Melendez, ANDA Consolidation Coordinator, at Kathleen.Melendez@fda.hhs.gov[1] or 240-402-2358.

Sincerely,

Kathleen M. Melendez -S

Digitally signed by Kathleen M. Melendez -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001757355, cn=Kathleen M. Melendez -S
Date: 2016.09.02 10:41:35 -04'00'

Kathleen Melendez, Pharmacist
Division of Filing Review
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

[1] Secure email between CDER and applicants may be useful for informal communications when confidential information may be included in the message (for example, trade secrets or patient information). If you have not already established secure email with FDA and would like to set it up, send an email request to SecureEmail@fda.hhs.gov. Please note that secure email may not be used for formal regulatory submissions to applications.

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

/s/

KATHLEEN M MELENDEZ
09/02/2016

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 71-745

RECEIVED
SEP 14 1988
REGULATORY AFFAIRS

SEP 12 1988

Zenith Laboratories, Inc.
Attention: A. C. Hanzas
50 Williams Drive
Ramsey, New Jersey 07446

Dear Sir:

Reference is made to your abbreviated new drug application dated December 22, 1986, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Prazosin Hydrochloride Capsules USP, 5 mg.

Reference is also made to your communications dated July 29, August 25, 26, 29, 30 and September 7, 1988.

Your application contains certifications with regards to three applicable patents.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved; however the effective date of approval is delayed until May 16, 1989 pursuant to 21 U.S.C. 355(j)(4)(B) relating to patent rights because Patent Number 3,663,706 does not expire until May 16, 1989. Patent Number 4,092,315 expires May 30, 1995; however, Zenith claimed noninfrigement, notified the patent holder and no suit was brought within 45 days. Patent Number 4,130,647 expires December 19, 1995; however, it is for a condition of use for which Zenith is not seeking approval.

This Division should be advised of any change in the marketing status of this drug. Thus, if circumstances arise which may have impact upon the effective date of approval (e.g. a license agreement between you and the patent holder), you are requested to supplement your application with documentation from the patent holder that a licensing agreement exists and include any relevant conditions or restrictions.

Any significant change in the conditions outlined in this abbreviated application including a change in the effective date of approval requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 314.70 of the new drug regulations.

Postmarketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80 and 314.81 of the Regulations.

For Intital Campaigns: We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your immediate advertising or promitional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Advertising and Labeling (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

For Subsequent Campaigns: We call your attention to Section 314.81(b)(3) of the Regulations which requires that materials for any subsequent advertising or promotional campaign, at the time of their initial use, be submitted to our Division of Drug Advertising and Labeling (HFD-240) with a completed Form FD-2253.

The introduction or delivery for introduction into interstate commerce of the drug before the effective approval date is prohibited under 21 U.S.C. 331(d).

Sincerely yours,

Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 71-994

RECEIVED
SEP 14 1988
REGULATORY AFFAIRS

SEP 12 1988

Zenith Laboratories, Inc.
Attention: A. C. Hanzas
50 Williams Drive
Ramsey, New Jersey 07446

Dear Sir:

Reference is made to your abbreviated new drug application dated April 22, 1987, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Prazosin Hydrochloride Capsules USP, 1 mg.

Reference is also made to your communications dated July 29, August 25, 26, 29, 30 and September 7, 1988.

Your application contains certifications with regards to three applicable patents.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved; however the effective date of approval is delayed until May 16, 1989 pursuant to 21 U.S.C. 355(j)(4)(B) relating to patent rights because Patent Number 3,663,706 does not expire until May 16, 1989. Patent Number 4,092,315 expires May 30, 1995; however, Zenith claimed noninfrigement, notified the patent holder and no suit was brought within 45 days. Patent Number 4,130,647 expires December 19, 1995; however, it is for a condition of use for which Zenith is not seeking approval.

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Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 71-995

Zenith Laboratories, Inc.
Attention: A. C. Hanzas
50 Williams Drive
Ramsey, New Jersey 07446

RECEIVED
SEP 14 1988
REGULATORY AFFAIRS

[redacted]

Dear Sir:

Reference is made to your abbreviated new drug application dated April 22, 1987, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Prazosin Hydrochloride Capsules USP, 2 mg.

Reference is also made to your communications dated July 29, August 25, 26, 29, 30 and September 7, 1988.

Your application contains certifications with regards to three applicable patents.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved; however the effective date of approval is delayed until May 16, 1989 pursuant to 21 U.S.C. 355(j)(4)(B) relating to patent rights because Patent Number 3,663,706 does not expire until May 16, 1989. Patent Number 4,092,315 expires May 30, 1995; however, Zenith claimed noninfrigement, notified the patent holder and no suit was brought within 45 days. Patent Number 4,130,647 expires December 19, 1995; however, it is for a condition of use for which Zenith is not seeking approval.

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Sincerely yours,

Marvin Seife, M.D.
Director
Division of Generic Drugs
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