CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-441

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 8 2002

[redacted]

Dear [redacted]

Between September 3 and 9, 2002, Dana M. Daigle, representing the Food and Drug Administration (FDA), met with you to review your conduct of a clinical study (protocol #AD-99-02 entitled: "Advil Multi-Symptom Allergy Sinus Efficacy and Safety Study") of the investigational drug Advil Multi-Symptom Allergy Sinus (ibuprofen/pseudoephedrine/chlorpheniramine), performed for Whitehall-Robins Healthcare. This inspection is a part of FDA's Bioresearch Monitoring Program, which includes inspections designed to validate clinical studies on which drug approval may be based and to ensure that the rights and welfare of the human subjects of those studies have been protected.

From our evaluation of the inspection report and the documents submitted with that report, we conclude that you did adhere to FDA regulations governing your conduct of clinical investigations and the protection of human subjects

We appreciate the cooperation shown Investigator Daigle during the inspection. Should you have any questions or concerns regarding this letter or the inspection, please contact me by letter, at the address given below.

Sincerely yours,

/S/

Antoine El-Hage, Ph.D.
Associate Director
Good Clinical Practice Branch I & II, HFD-46/47
Division of Scientific Investigations
Office of Medical Policy
Center for Drug Evaluation and Research
7520 Standish Place, Room 125
Rockville, MD 20855

APPEARS THIS WAY
ON ORIGINAL

FEI: [redacted]
Field Classification: NAI
Headquarters Classification:
__X__1)NAI
_____2)VAI- no response required
_____3)VAI- response requested
_____4)OAI

If Headquarters classification is a different classification, explain why:

Deficiencies noted: **none**
Deficiency Codes: N/A

cc:
HFA-224
HFD-550 Doc.Rm. NDA# 21-441
HFD-550 Review Div.Dir. Simon
HFD-550 MO Fang
HFD-550 PM Dean
HFD-47c/r/s/ GCP File # 10709
HFD-47 GCP Reviewer Shibuya
HFD-47 CSO Mease
HFR-SE450 DIB Debo
HFR-SE450 BIMO Monitor Roosevelt
HFR-SE4550 Field Investigator Daigle
r/d: MM:10/4/02
reviewed:AEH:10/7/02
f/t:ml:10/8/02

o:\MM\ [redacted] NAI 10_02.doc

Reviewer Note to Rev. Div. M.O.

The FDA Inspector reviewed 15 randomly selected subject records and compared the data to the sponsor's data line listings. Generally, the 15 subjects' records were in order and acceptable.

[redacted] screened 55 patients and enrolled 32 subjects. Subjects 10352 and 11231 took study drug dose 2 on day 1 prematurely; the sponsor discontinued these two subjects due to protocol violations. Subject 10352 also took a prohibited medication (Flexeril). Subject 10346 took a prohibited medication (Wellbutrin).

Overall, the data are acceptable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-441

Wyeth Consumer Healthcare
Attention: Sharon C. Heddish
Vice President, Regulatory Affairs-Worldwide
Five Giralda Farms
Madison, NJ 07940-0871

Dear Ms. Heddish:

We acknowledge receipt on 12 March 2002 of your 11 March 2002 correspondence notifying the Food and Drug Administration that the corporate name has been changed from

Whitehall-Robins Healthcare
Five Giralda Farms
Madison, NJ 07940-0871

to

Wyeth Consumer Healthcare
Faive Giralda Farms
Madison, NJ 079040-0871

for the following new drug application:

NDA 21-441 Advil Allergy Sinus.

We revised our records to reflect this change.

Address all communications concerning this NDA as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
9201 Corporate Boulevard
Rockville, Maryland 20850

If you have any question, please call Ms. Jane A. Dean, RN, MSN, Regulatory Health Project Manager, at (301)827-2090.

Sincerely,

/S/

{See appended electronic signature page}

Carmen DeBellas, R. Ph.
Chief, Project Management Staff
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

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

/s/

Carmen DeBellas
3/20/02 10:42:41 AM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-441

Whitehall-Robins Healthcare
Attention: Mary H. Davis, Director, Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Ms. Davis:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	Advil Allergy Sinus Caplet (ibuprofen 200mg/ pseudoephedrine 30mg/chlorpheniramine 2mg caplet)
Review Priority Classification:	Standard (S)
Date of Application:	28 February 2002
Date of Receipt:	1 March 2002
Our Reference Number:	NDA 21-441

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on 29 April 2002 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be 1 January 2003.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. Address all communications concerning this NDA as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
9201 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions, please call Ms. Jane A. Dean, RN, MSN, Regulatory Health Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Carmen DeBellas, R. Ph.
Chief, Project Management Staff
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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

/s/

Carmen DeBellas
4/18/02 05:47:31 PM