DIV

NDA 12-770/S-024

JUL 29 1997

Wallace Laboratories
Division of Carter-Wallace, Inc.
Attention: Ilona J. Scott
Director, Regulatory Affairs
P.O. Box 1001
Half Acre Road
Cranbury, NJ 08512

Dear Ms. Scott:

Please refer to your supplemental new drug application dated April 4, 1997, received April 7, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vosol® HC (hydrocortisone and acetic acid otic solution, USP) Otic Solution.

We acknowledge receipt of your submissions dated April 7, May 30, and July 9, 1997.

This supplemental application provides for a revised package insert to add a Pediatric Use subsection to the Precautions section.

We have completed the review of this supplemental application including the submitted draft labeling and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling in the submission dated April 4, 1997 with the revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter. As discussed by telephone on July 8, 1997, between you and Ms. Joanne Holmes of this Division, the following revisions will be made:

1. The Pediatric Use subsection of the Precautions section will be revised to read: "Safety and effectiveness in pediatric patients below the age of 3 years have not been established."

2. The word "controlled" will be deleted from the Storage section.

These revisions are terms of the supplemental NDA approval.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved supplemental NDA 12-770/S-024. Approval of this submission of FPL by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Joanne M. Holmes, M.B.A., Clinical Reviewer, at (301) 827-2090.

Sincerely,

MW 7/29/97

Michael Weintraub, M.D.
Acting Director
Division of Anti-Inflammatory, Analgesic, and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research