DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 12-802/S-014, S-016

Fujisawa Healthcare, Inc.
Attention: Donald E. Baker, J.D.
Senior Director, Regulatory Affairs
Three Parkway North
Deerfield, IL 60015-2548

Dear Mr. Baker:

Please refer to your supplemental new drug applications dated September 20, 1985, and June 5, 1986, and received September 26, 1985, and June 9, 1986, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aristocort® Forte (triamcinolone diacetate injectable suspension, USP) Parenteral 40 mg/mL.

We acknowledge receipt of your submissions dated October 9, 2002, and received October 10, 2002.

Your submission of October 9, 2002, constituted a complete response to our April 6, 2001, action letter.

These supplemental new drug applications provide for draft labeling identical in content to the April 6, 2001, approvable letter with exceptions related to the transfer of ownership of the product.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted October 9, 2002).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper 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, these submissions should be designated "FPL for approved supplement NDA 12-802/S-014, S-016." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Stacey N. Welch, Regulatory Health Project Manager, at 301-827-2496.

Sincerely,

{See appended electronic signature page}

Lee S. Simon, M.D.
Director
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/

Lee Simon

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