DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021844/S-002 **SUPPLEMENT APPROVAL**

Intendis, Inc.
Attention: Elena Serbinova, Ph.D., RAC
Director, Drug Regulatory Affairs
36 Columbia Road
P.O. Box 1941
Morristown, NJ 07962

Dear Dr. Serbinova:

Please refer to your supplemental new drug application dated June 30, 2009, received July 1, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Desonate (desonide) Gel, 0.05%.

We acknowledge receipt of your submissions dated August 17, September 21, November 24, and December 3, 2009.

This supplement provides for the revision of the Desonate Gel full prescribing information to meet the new labeling content and format requirements for human prescription drug and biological products according to 21 CFR 201.56(d) and 201.57.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling text for the package insert. For administrative purposes, please designate this submission, "**SPL for approved NDA 021844/S-002**".

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Tamika White, Regulatory Project Manager, at (301) 796-0310.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, M.D., M.P.H.
Deputy Director for Safety
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21844	SUPPL-2	INTENDIS INC	DESONATE HYDROGEL (DESONIDE GEL 0.05%)

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

/s/

TATIANA OUSSOVA
12/29/2009