



NDA 20-675/S-013

Axcan Scandipharm, Inc.  
c/o: CanReg, Inc.  
Attention: Irma Monaco  
Manager, Regulatory Affairs (CMC)  
450 North Lakeshore Drive  
Mundelein, IL 60060

Dear Ms. Monaco:

Please refer to your supplemental new drug application dated January 19, 2007, received January 22, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Urso Forte (ursodiol, USP) Tablets, 500 mg.

We acknowledge receipt of your submissions dated February 21, March 22, August 1 (email), and December 7, 2007.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of scoring to the Urso Forte 500 mg Tablets.

We completed our review of this application, as amended. This application is 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 enclosed labeling (text for the package insert, immediate container and carton labels), which are identical to your submission dated December 7, 2007.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-675/S-013.**" Approval of this submission 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  
Food and Drug Administration  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

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 Thomas Moreno, Regulatory Project Manager, at (301) 796-2247.

Sincerely,

*{See appended electronic signature page}*

Joyce Korvick, M.D., M.P.H.  
Deputy Director  
Division of Gastroenterology Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Joyce Korvick  
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