

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-222Orig1s000

OTHER ACTION LETTERS



NDA 022222

COMPLETE RESPONSE

Axcan Pharma U.S., Inc.
Attention: Guy Rousseau, Ph.D.
Vice President, Regulatory Affairs and Quality Assurance
22 Inverness Center Parkway
Birmingham, AL 35242

Dear Dr. Rousseau:

Please refer to your New Drug Application (NDA) dated September 28, 2007, received October 1, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ultresa (pancrelipase) Delayed-Release Capsules.

We acknowledge receipt of your amendments dated October 23, 2007; October 26, 2007; December 11, 2007; December 20, 2007; December 21, 2007; January 8, 2008; January 21, 2008; February 1, 2008; February 14, 2008; March 10, 2008; April 17, 2008; May 9, 2008; July 4, 2008; August 6, 2008; September 16, 2008; October 20, 2008; April 7, 2009; May 7, 2009; June 2, 2009; June 12, 2009; July 7, 2009; July 13, 2009; July 14, 2009; July 31, 2009; August 4, 2009; August 17, 2009; September 8, 2009; September 15, 2009; September 28, 2009; October 30, 2009; November 5, 2009; November 19, 2009; November 27, 2009; February 19, 2010; March 8, 2010; March 10, 2010; March 12, 2010; March 29, 2010; April 6, 2010; April 28, 2010; May 4, 2010; May 5, 2010; May 6, 2010; May 11, 2010; May 27, 2010; May 28, 2010; June 21, 2010; July 1, 2010; July 12, 2010; July 20, 2010; August 3, 2010; August 6, 2010; August 12, 2010; August 27, 2010; October 1, 2010, October 19, 2010, October 21, 2010, and November 15, 2010.

The May 28, 2010, submission constituted a complete response to our May 5, 2010, action letter.

We also acknowledge receipt of your amendments dated October 26, 2010, November 9, 2010, November 18, 2010, and November 23, 2010, which received a preliminary review for this action. You may incorporate these amendments by specific reference as part of your response to the deficiencies cited in this letter.

We have completed our review of this application, as amended, and have determined that we cannot approve this application in its present form. We have described our reasons for this action below and, where possible, our recommendations to address these issues.

PRODUCT QUALITY

(b) (4) DMF # (b) (4) has been reviewed in support of NDA 022222 and found to contain deficiencies. A letter dated October 27, 2010, was sent to (b) (4) listing several deficiencies regarding the drug substance manufacturing process. FDA conveyed additional information requests at a face-to-face meeting held on November 15, 2010, with you and representatives from (b) (4) should address all deficiencies by directly submitting information to their DMF, or, if the information was previously submitted, then by specific reference to the appropriate submissions. Please notify us when (b) (4) has submitted the requested information. Satisfactory resolution of the deficiencies identified is required before this application may be approved.

FACILITY INSPECTIONS

During an inspection of a manufacturing facility referenced in this application, (b) (4) (b) (4) conducted between (b) (4) and (b) (4), the FDA investigator conveyed deficiencies to a representative of the facility. (b) (4) response dated (b) (4) addressing the deficiencies listed on FDA form 483 dated (b) (4) was not adequate. Satisfactory resolution of these deficiencies is required before this application may be approved.

LABELING

We reserve comment on the proposed labeling until the application is otherwise adequate. If you revise labeling, your response must include updated content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

As described in our letter dated May 20, 2009, in accordance with section 505-1 of the FDCA, we have determined that a risk evaluation and mitigation strategy (REMS) is necessary for Ultresa (pancrelipase) Delayed-Release Capsules to ensure that the benefits of the drug outweigh the risk of fibrosing colonopathy associated with higher doses of pancreatic enzyme products (PEPs), and the theoretical risk of transmission of viral disease to patients.

We acknowledge the submission of your proposed REMS on June 2, 2009, which contains a Medication Guide and a timetable for submission of assessments of the REMS. We will continue discussion of your proposed REMS after your complete response to this action letter has been submitted.

For administrative purposes, designate all submissions related to the proposed REMS “**PROPOSED REMS-AMENDMENT for NDA 022222.**”

If you do not submit electronically, please send 5 copies of your REMS-related submissions.

SAFETY UPDATE

When you respond to the above deficiencies, include a safety update as described at 21 CFR 314.50(d)(5)(vi)(b). The safety update should include data from all nonclinical and clinical studies/trials of the drug under consideration regardless of indication, dosage form, or dose level.

1. Describe in detail any significant changes or findings in the safety profile.
2. When assembling the sections describing discontinuations due to adverse events, serious adverse events, and common adverse events, incorporate new safety data as follows:
 - Present new safety data from the studies/clinical trials for the proposed indication using the same format as the original NDA submission.
 - Present tabulations of the new safety data combined with the original NDA data.
 - Include tables that compare frequencies of adverse events in the original NDA with the retabulated frequencies described in the bullet above.
 - For indications other than the proposed indication, provide separate tables for the frequencies of adverse events occurring in clinical trials.
3. Present a retabulation of the reasons for premature trial discontinuation by incorporating the drop-outs from the newly completed trials. Describe any new trends or patterns identified.
4. Provide case report forms and narrative summaries for each patient who died during a clinical trial or who did not complete a trial because of an adverse event. In addition, provide narrative summaries for serious adverse events.
5. Describe any information that suggests a substantial change in the incidence of common, but less serious, adverse events between the new data and the original NDA data.
6. Provide updated exposure information for the clinical studies/trials (e.g., number of subjects, person time).
7. Provide a summary of worldwide experience on the safety of this drug. Include an updated estimate of use for drug marketed in other countries.
8. Provide English translations of current approved foreign labeling not previously submitted.

POSTMARKETING REQUIREMENTS UNDER 505(o)(3)

As described in our letter dated September 9, 2009, we have determined that if this application is approved, you will be required to conduct postmarketing studies for Ultresa (pancrelipase) Delayed-Release Capsules to assess a known serious risk of fibrosing colonopathy and an

unexpected serious risk of transmission of viral disease to patients taking Ultresa (pancrelipase) Delayed-Release Capsules.

1. A 10 year, observational study to prospectively evaluate the incidence of fibrosing colonopathy in patients with cystic fibrosis treated with Ultresa (pancrelipase) Delayed-Release Capsules in the US and to assess potential risk factors for the event.
2. A 10 year, observational study to prospectively evaluate the risk of transmission of selected porcine viruses in patients taking Ultresa (pancrelipase) Delayed-Release Capsules.

Any additional specific details for these required postmarketing studies, including a timetable and annual reporting requirements, will be described more fully in the approval letter for this application, if it is approved.

If you complete one or both of these studies prior to re-submitting your application, you may include the final report(s) and relevant data sets in your Complete Response submission to facilitate review of the information.

OTHER

Within one year after the date of this letter, you are required to resubmit or take other actions available under 21 CFR 314.110. If you do not take one of these actions, we may consider your lack of response a request to withdraw the application under 21 CFR 314.65. You may also request an extension of time in which to resubmit the application. A resubmission must fully address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the FDA's "Guidance for Industry - Formal Meetings Between the FDA and Sponsors or Applicants," May 2009 at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf>.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, call Elizabeth Ford, Regulatory Project Manager, at (301) 796-0193.

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Director
Office of Drug Evaluation III
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/

JULIE G BEITZ
11/28/2010



NDA 022222

COMPLETE RESPONSE

Axcan Pharma US, Inc.
c/o CanReg Inc.
Attention: Nicole Brufatto, Ph.D., RAC
Director, US Regulatory Affairs
450 North Lakeshore Drive
Mundelein, IL 60060

Dear Dr. Brufatto:

Please refer to your September 28, 2007 New Drug Application (NDA), received October 1, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ultresa (pancrelipase) Delayed-Release Capsules.

We acknowledge receipt of your submissions dated July 31, 2007, August 17, 2007, August 20, 2007, September 11, 2007, September 27, 2007, September 28, 2007, October 23, 2007, October 26, 2007, December 11, 2007, December 20, 2007, December 21, 2007, January 8, 2008, January 21, 2008, February 1, 2008, February 14, 2008, March 10, 2008, April 17, 2008, May 9, 2008, July 4, 2008, August 6, 2008, September 16, 2008, October 20, 2008, April 7, 2009, May 7, 2009, June 12, 2009, July 7, 2009, July 13, 2009, July 14, 2009, July 31, 2009, August 4, 2009, August 17, 2009, September 8, 2009, September 15, 2009, September 28, 2009, October 30, 2009, November 5, 2009, November 19, 2009, November 27, 2009, February 19, 2010, March 8, 2010, March 10, 2010, March 12, 2010, March 29, 2010, April 6, 2010, and April 28, 2010.

The November 5, 2009 amendment constituted a complete response to our September 9, 2009 action letter.

We also acknowledge receipt of your amendment dated May 4, 2010, which was not reviewed for this action. You may incorporate applicable sections of the amendment by specific reference as part of your response to the deficiencies cited in this letter.

We have completed the review of your application, as amended, and have determined that we cannot approve this application in its present form. We have described below our reasons for this action and, where possible, our recommendations to address these issues.

PRODUCT QUALITY

1. The (b) (4) DMF # (b) (4) and the EURAND DMF #15681 have been reviewed in support of NDA 022222 and found to contain deficiencies.

Letters have been sent to (b) (4) and EURAND listing the deficiencies. (b) (4) and EURAND should address the deficiencies by directly submitting information to their respective DMFs. Please notify us when (b) (4) and EURAND have submitted the requested information.

2. We noted a discrepancy in the description of the capsules printing between your NDA submission and the description provided in the package insert. Please amend your NDA submission to be consistent with the information provided in the package insert.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

3. As described in our letter dated May 20, 2009, in accordance with section 505-1 of the FDCA, we have determined that a REMS is necessary for Ultresa (pancrelipase) Delayed-Release Capsules and other porcine-derived pancreatic enzyme products (PEPs) to ensure that the benefits of the drug outweigh the risk of fibrosing colonopathy associated with higher doses of PEPs, and the theoretical risk of transmission of viral disease to patients.

We acknowledge receipt of your proposed REMS submitted on June 2, 2009 which contains a Medication Guide and a timetable for submission of assessments of the REMS. We will continue discussion of your proposed REMS after your complete response to this action letter has been submitted.

Prominently identify submissions related to the proposed REMS with the following wording in bold capital letters at the top of the first page of the submission:

**NDA 022222
PROPOSED REMS-AMENDMENT**

If you do not submit electronically, please send 5 copies of your REMS-related submissions.

LABELING

4. We reserve comment on the proposed labeling until the application is otherwise adequate. If you revise labeling, your response must include updated content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

FACILITY INSPECTIONS

During a recent inspection of the (b) (4) manufacturing facility for this application, our field investigator conveyed deficiencies to the representative of the facility. Satisfactory resolution of these deficiencies is required before this application may be approved.

SAFETY UPDATE

When you respond to the above deficiencies, include a safety update as described at 21 CFR 314.50(d)(5)(vi)(b). The safety update should include data from all nonclinical and clinical studies/trials of the drug under consideration regardless of indication, dosage form, or dose level.

1. Describe in detail any significant changes or findings in the safety profile.
2. When assembling the sections describing discontinuations due to adverse events, serious adverse events, and common adverse events, incorporate new safety data as follows:
 - Present new safety data from the studies/clinical trials for the proposed indication using the same format as the original NDA submission.
 - Present tabulations of the new safety data combined with the original NDA data.
 - Include tables that compare frequencies of adverse events in the original NDA with the retabulated frequencies described in the bullet above.
 - For indications other than the proposed indication, provide separate tables for the frequencies of adverse events occurring in clinical trials.
3. Present a retabulation of the reasons for premature trial discontinuation by incorporating the drop-outs from the newly completed trials. Describe any new trends or patterns identified.
4. Provide case report forms and narrative summaries for each patient who died during a clinical trial or who did not complete a trial because of an adverse event. In addition, provide narrative summaries for serious adverse events.
5. Describe any information that suggests a substantial change in the incidence of common, but less serious, adverse events between the new data and the original NDA data.
6. Provide updated exposure information for the clinical studies/trials (e.g., number of subjects, person time).
7. Provide a summary of worldwide experience on the safety of this drug. Include an updated estimate of use for drug marketed in other countries.
8. Provide English translations of current approved foreign labeling not previously submitted.

POSTMARKETING REQUIREMENTS UNDER 505(o)

As described in our action letter dated September 9, 2009, in accordance with section 505(o)(3) of the FDCA, we have determined that, if this application is approved, you will be required to

conduct the following postmarketing studies of Ultresa (pancrelipase) to assess a known serious risk of fibrosing colonopathy and the unexpected serious risk of transmission of viral disease to patients taking Ultresa (pancrelipase) Delayed-Release Capsules:

1. A 10 year, observational study to prospectively evaluate the incidence of fibrosing colonopathy in patients with cystic fibrosis treated with Ultresa (pancrelipase) Delayed-Release Capsules in the US and to assess potential risk factors for the event.
2. A 10 year, observational study to prospectively evaluate the risk of transmission of selected porcine viruses in patients taking Ultresa (pancrelipase) Delayed-Release Capsules.

The specific details of these required postmarketing studies, including a timetable and annual reporting requirements, will be described more fully in the approval letter for this application, if it is approved.

OTHER

Within one year after the date of this letter, you are required to resubmit or take one of the other actions available under 21 CFR 314.110. If you do not take one of these actions, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. A resubmission must fully address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the FDA's *Guidance for Industry - Formal Meetings Between the FDA and Sponsors or Applicants*, May 2009 at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf>.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, call Elizabeth Ford, Regulatory Project Manager, at (301) 796-0193.

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22222

ORIG-1

AXCAN
SCANDIPHARM
INC

ULTRASE MT 12, 18, 20
CAPSULES

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/s/

JULIE G BEITZ
05/05/2010



NDA 022222

COMPLETE RESPONSE

Axcan Pharma US, Inc.
c/o CanReg Inc.
Nicole Brufato, Ph.D., RAC
Director, US Regulatory Affairs
450 North Lakeshore Drive
Mundelein, IL 60060

Dear Dr. Brufato:

Please refer to your new drug application (NDA) dated September 28, 2007, received October 1, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TRADENAME (pancrelipase, USP) Capsules.

We acknowledge receipt of your submissions dated July 31, 2007; August 17 and 20, 2007; September 11, 27 and 28, 2007; October 23 and 26, 2007; December 11, 20, and 21, 2007, January 8 and 21, 2008; February 1 and 14, 2008; March 10, 2008; April 17, 2008; May 9, 2008; July 4, 2008; August 6, 2008; September 16, 2008; October 20, 2008; April 7, 2009; May 7, 2009; June 12, 2009; July 7, 13, 14, and 31, 2009; and August 4, 2009.

The April 7, 2009 submission constituted a complete response to our July 1, 2008 action letter.

We also acknowledge receipt of your submissions dated June 2, 2009, August 17, 2009, and September 8, 2009, which were not reviewed for this action. You may incorporate applicable sections of these submissions by specific reference as part of your response to the deficiencies cited in this letter.

Furthermore, we acknowledge receipt of your submission of your proposed proprietary name, received July 7, 2009. We will complete the review and will issue a letter regarding our decision by October 5, 2009. Should you choose to submit a complete response to this action letter, you will then need to submit a new request for proprietary name review.

We have completed the review of your application, as amended, and have determined that we cannot approve this application in its present form. We have described below our reasons for this action and, where possible, our recommendations to address these issues.

PRODUCT QUALITY

1. The (b) (4) ((b) (4) DMF # (b) (4) and the EURAND DMF #15681 have been reviewed in support of NDA 022222 and found to contain deficiencies. Letters will be sent to (b) (4) and EURAND listing the deficiencies. (b) (4) and EURAND should address the deficiencies by directly submitting information to their respective DMFs. Please notify us when (b) (4) and EURAND have submitted the requested information.
2. Your annual stability data (Batches D070151C, D070151A, F070244B, F070244A, F070224D, F070224A, D070145B, C080114D, C080114C, D080118A, D080118C, D080151C, C080115A, D080119A) indicate that stability tests are performed before the product is packaged in its final container/closure system. Clarify if all stability studies you have performed were conducted on drug product prior to final packaging. Stability studies should be performed on packaged drug product using the final container/closure system.
3. Submit stability data collected using the updated stability program and acceptance criteria submitted in the NDA.
4. You have not provided a study that addressed the stability of the product once the final container is opened by the pharmacist or by the patient. Provide forced degradation studies (i.e. photostability, moisture conditions, etc.) conducted on the drug product to support in-use stability of drug product.
5. The stability data you have provided for the 12 count bottle only support a 12 month expiry. Revise your label accordingly, or provide additional data to support your requested dating period of 16 months.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

6. As described in our letter dated May 20, 2009, in accordance with section 505-1 of the FDCA, we have determined that a REMS is necessary for TRADENAME (pancrelipase, USP) Capsules and other porcine-derived pancreatic enzyme products (PEPs) to ensure that the benefits of the drug outweigh the risk of fibrosing colonopathy associated with higher doses of PEPs, and the theoretical risk of transmission of viral disease to patients.

We acknowledge the submission of your REMS documents on June 2, 2009. Once FDA finds the content of your REMS acceptable and determines that the application can be approved, we will include these documents as an attachment to the approval letter that includes the REMS.

Under 21 CFR 208.24(d), you are responsible for ensuring that the label of each container or package includes a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and states

how the Medication Guide is provided. You should submit marked up carton and container labels of all strengths and formulations with the required statement alerting the dispenser to provide the Medication Guide. We recommend the following language dependent upon whether the Medication Guide accompanies the product or is enclosed in the carton (for example, unit of use):

“Dispense the enclosed Medication Guide to each patient.” or

“Dispense the accompanying Medication Guide to each patient.”

Prominently identify submissions related to the proposed REMS with the following wording in bold capital letters at the top of the first page of the submission:

NDA 022222
PROPOSED REMS-AMENDMENT

If you do not submit electronically, please send 5 copies of your REMS-related submissions.

LABELING

7. We reserve comment on the proposed labeling until the application is otherwise adequate. If you revise labeling, your response must include updated 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>.

FACILITY INSPECTIONS

During a recent inspection of the [REDACTED] ^{(b) (4)} manufacturing facility for this application, our field investigator conveyed deficiencies to the representative of the facility. Satisfactory resolution of these deficiencies is required before this application may be approved.

SAFETY UPDATE

When you respond to the above deficiencies, include a safety update as described at 21 CFR 314.50(d)(5)(vi)(b). The safety update should include data from all nonclinical and clinical studies/trials of the drug under consideration regardless of indication, dosage form, or dose level.

1. Describe in detail any significant changes or findings in the safety profile.
2. When assembling the sections describing discontinuations due to adverse events, serious adverse events, and common adverse events, incorporate new safety data as follows:

- Present new safety data from the studies for the proposed indication using the same format as the original NDA submission.
 - Present tabulations of the new safety data combined with the original NDA data.
 - Include tables that compare frequencies of adverse events in the original NDA with the retabulated frequencies described in the bullet above.
 - For indications other than the proposed indication, provide separate tables for the frequencies of adverse events occurring in clinical trials.
3. Present a retabulation of the reasons for premature study discontinuation by incorporating the drop-outs from the newly completed studies. Describe any new trends or patterns identified.
 4. Provide case report forms and narrative summaries for each patient who died during a clinical study or who did not complete a study because of an adverse event. In addition, provide narrative summaries for serious adverse events.
 5. Describe any information that suggests a substantial change in the incidence of common, but less serious, adverse events between the new data and the original NDA data.
 6. Provide updated exposure information for the clinical studies/trials (e.g., number of subjects, person time).
 7. Provide a summary of worldwide experience on the safety of this drug. Include an updated estimate of use for drug marketed in other countries.
 8. Provide English translations of current approved foreign labeling not previously submitted.

POSTMARKETING REQUIREMENTS UNDER 505(o)

Section 505(o) of the FDCA authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (section 505(o)(3)(A)).

We have determined that an analysis of spontaneous postmarketing adverse events reported under subsection 505(k)(1) of the FDCA will not be sufficient to assess a known serious risk of fibrosing colonopathy and the unexpected serious risk of transmission of viral disease to patients taking TRADENAME (pancrelipase, USP) Capsules.

Furthermore, the new pharmacovigilance system that FDA is required to establish under section 505(k)(3) of the FDCA has not yet been established and is not sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, FDA has determined that, if this application is approved, you will be required, pursuant to section 505(o)(3) of the FDCA, to conduct:

1. A 10 year, observational study to prospectively evaluate the incidence of fibrosing colonopathy in patients with cystic fibrosis treated with TRADENAME (pancrelipase, USP) Capsules in the US and to assess potential risk factors for the event.
2. A 10 year, observational study to prospectively evaluate the risk of transmission of selected porcine viruses in patients taking TRADENAME (pancrelipase, USP) Capsules.

The specific details of these required postmarketing studies will be described more fully in the approval letter for this application, if it is approved.

OTHER

Within one year after the date of this letter, you are required to resubmit or take one of the other actions available under 21 CFR 314.110. If you do not take one of these actions, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. A resubmission must fully address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the FDA's *Guidance for Industry - Formal Meetings Between the FDA and Sponsors or Applicants*, May 2009 at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf>.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, call Elizabeth Ford, Regulatory Project Manager, at (301) 796-0193.

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22222

ORIG-1

AXCAN
SCANDIPHARM
INC

ULTRASE MT 12, 18, 20
CAPSULES

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/s/

JULIE G BEITZ
09/09/2009