CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-542Orig1s000

RISK ASSESSMENT and RISK MITIGATION REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date: July 19, 2010

To: Donna Griebel, MD, Director
Division of Gastroenterology Products (DGP)

Through: Claudia Karwoski, PharmD, Director
Division of Risk Management (DRISK)
Sharon R. Mills, BSN, RN, CCRP
Senior Patient Labeling Reviewer, Acting Team Leader
Division of Risk Management

From: Steve L. Morin, RN, BSN
Patient Labeling Reviewer
Division of Risk Management

Subject: DRISK Review of Patient Labeling (Medication Guide), Proposed Risk Evaluation and Mitigation Strategy (REMS)

Drug Name(s): VIOKACE (pancrelipase) Tablets

Application Type/Number: NDA 22-542

Applicant/sponsor: Axcan Pharma US, Inc

OSE RCM #: 2009-2183

1 INTRODUCTION

This memorandum is in response to a request by the Division of Gastroenterology Products (DGP) for the Division of Risk Management (DRISK) to review the proposed Medication Guide (MG), proposed Risk Evaluation and Mitigation Strategy (REMS), and REMS supporting document for VIOKACE (pancrelipase) Tablet.

On April 28, 2009 Axcan Pharma US, Inc. submitted New Drug Application (NDA) 22-542 for VIOKACE (pancrelipase) Tablets under Section 505(b)(2) of the FD&C Act. Axcan Pharma US, Inc. voluntarily submitted a Risk Evaluation and Mitigation Strategy (REMS) for VIOKACE (pancrelipase) Tablets.

2 MATERIAL REVIEWED

- Draft VIOKACE (pancrelipase) Tablets Prescribing Information (PI) submitted March 9, 2010, revised by the review division throughout the review cycle and provided to DRISK on June 16, 2010
- Draft VIOKACE (pancrelipase) Tablets Medication Guide dated March 9, 2009, revised by the review division throughout the review cycle and provided to DRISK on July 09, 2010.
- Proposed VIOKACE (pancrelipase) Tablets Risk Evaluation and Mitigation Strategy (REMS) and REMS Supporting Document, submitted on October 29, 2009

3 RESULTS OF REVIEW

3.1 In our review of the Medication Guide, we have:

- Simplified wording and clarified concepts where possible
- Ensured that the MG is consistent with the PI
- Removed unnecessary or redundant information
- Ensured that the MG meets the Regulations as specified in 21 CFR 208.24
- Ensured that the MG meets the criteria as specified in FDA's Guidance Useful Written Consumer Medication Information (published July 2006)
- Referenced the approved MG for Pancreaze (NDA 22-523) for consistency

3.2 In our review of the proposed REMS and REMS Supporting Document, we have:

- Ensured it includes the elements outlined in the REMS Notification Letter
- Ensured it meets the statutory requirements under the Food and Drug Administration Amendments Act (FDAAA) of 2007.
- Reviewed the survey methodology for acceptability in assessing the goal of the REMS

4 CONCLUSIONS AND RECOMMENDATIONS

DRISK concurs with the elements of the REMS as proposed by the Applicant.

We have the following comments and recommendations for the Division of Gastroenterology Products (DGP)and Applicant with regard to the MG, the proposed REMS and the REMS Assessment methodology.

Comments to Review Division:
Please send these comments to the Applicant and request that they submit a response within two weeks of receipt. DRISK requests that DCRP copy us on the correspondence. Please let us know if you would like a meeting to discuss these comments before sending to the Applicant.

Our annotated MG is appended to this memo (Appendix A Marked Copy, Appendix B Clean Copy). Any additional revisions to the PI should be reflected in the MG.

Comments to Applicant Name:

a. See the appended VIOKACE (pancrelipase) REMS proposal for track changes corresponding to comments in this review.

b. GOAL

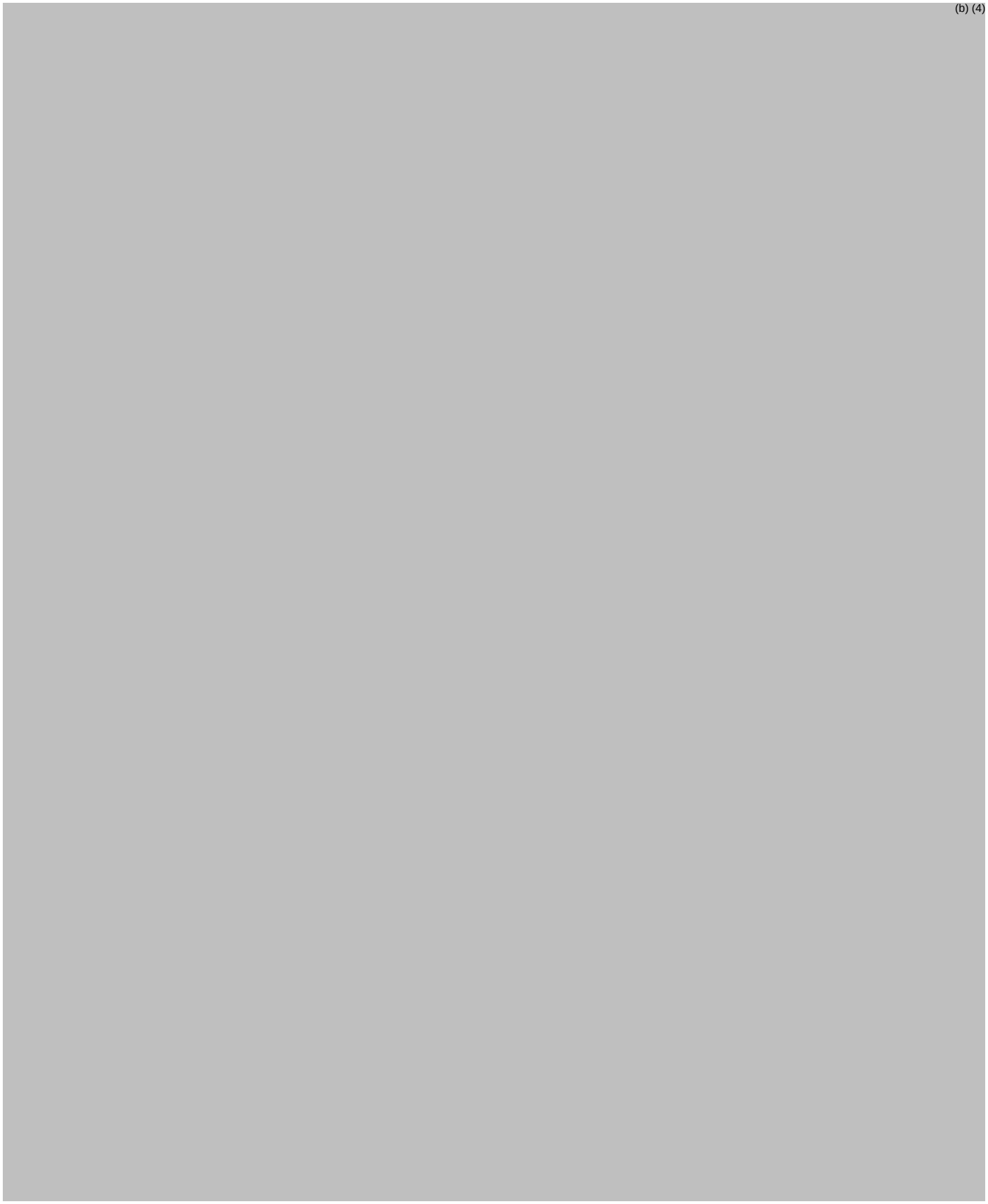
   Your proposed goal is acceptable.

c. Your plan to distribute the Medication Guide in accordance with 21 CFR 208.24 appears acceptable. The details of this plan should be moved to the REMS supporting document.

d. Your proposed timetable for submission of assessments (18 months, 3 years, and 7 years) is acceptable

   We have some editorial comments in this section of the proposed REMS.

e. Regarding your REMS Assessment Plan: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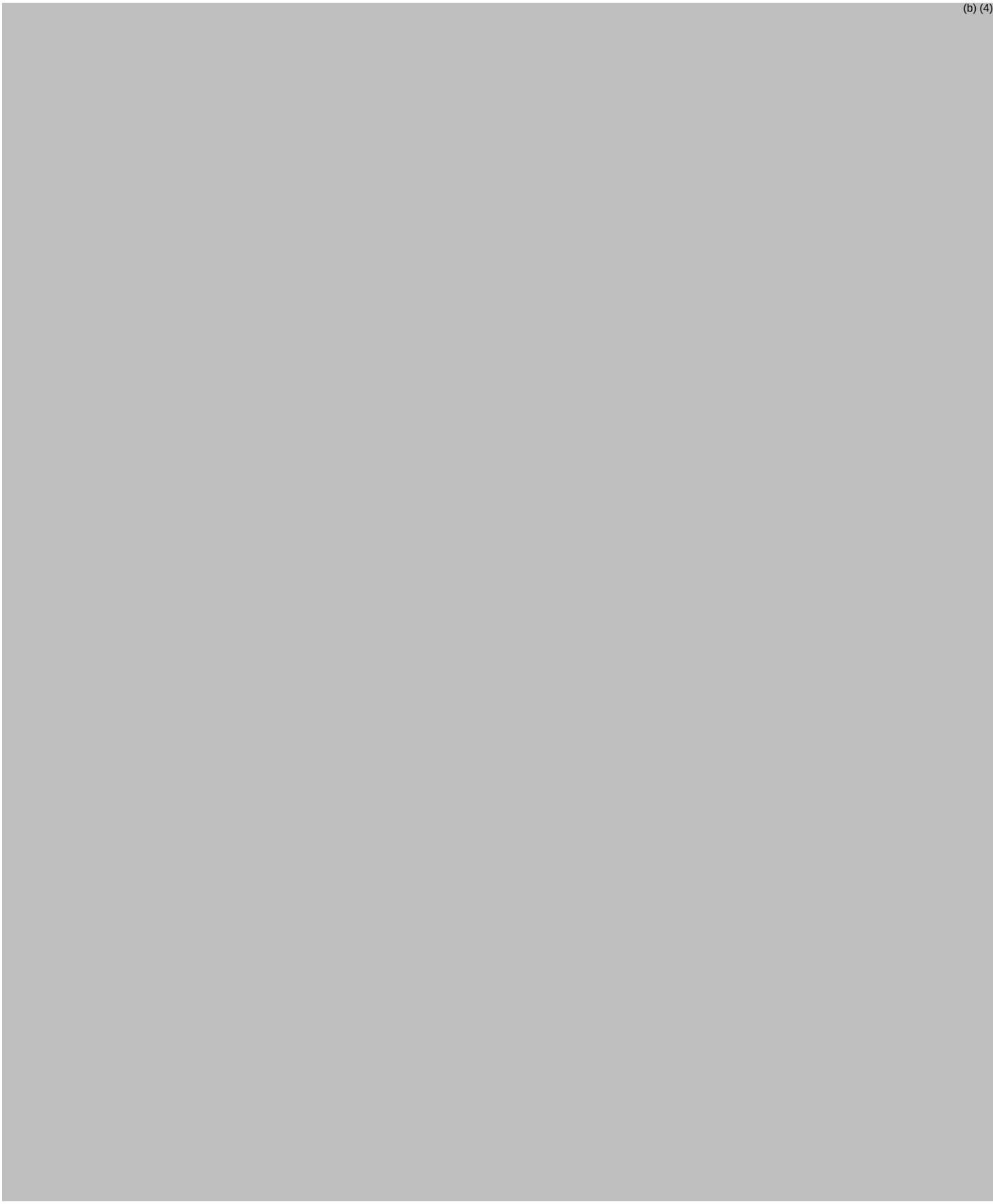
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f. Your proposal to monitor for adverse event reports associated with Viokace is acceptable.

12 pages of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22542	ORIG-1	AXCAN PHARMA US INC	VIOKASE (PANCRELIPASE)UNCOATED TABLETS

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

/s/

STEVE L MORIN
07/19/2010

CLAUDIA B KARWOSKI
07/19/2010
concur