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APPLICATION NUMBER:

22-076

OTHER REVIEW(S)

MEMORANDUM

To: Melinda Bauerlien
Division of Dermatology and Dental Products

From: Iris Masucci, PharmD, BCPS
Division of Drug Marketing, Advertising, and Communications
for the Study Endpoints and Label Development (SEALD) Team, OND

Date: May 1, 2007

Re: Comments on draft labeling for Locoid (hydrocortisone butyrate)
NDA 22-076

We have reviewed the proposed label for Locoid (FDA version incorporating the sponsor's accepted changes) and offer the following comments. These comments are based on Title 21 of the Code of Federal Regulations (201.56 and 201.57), the preamble to the Final Rule, labeling Guidances, and FDA recommendations to provide for labeling quality and consistency across review divisions. We recognize that final labeling decisions rest with the review division after a full review of the submitted data.

GENERAL COMMENTS

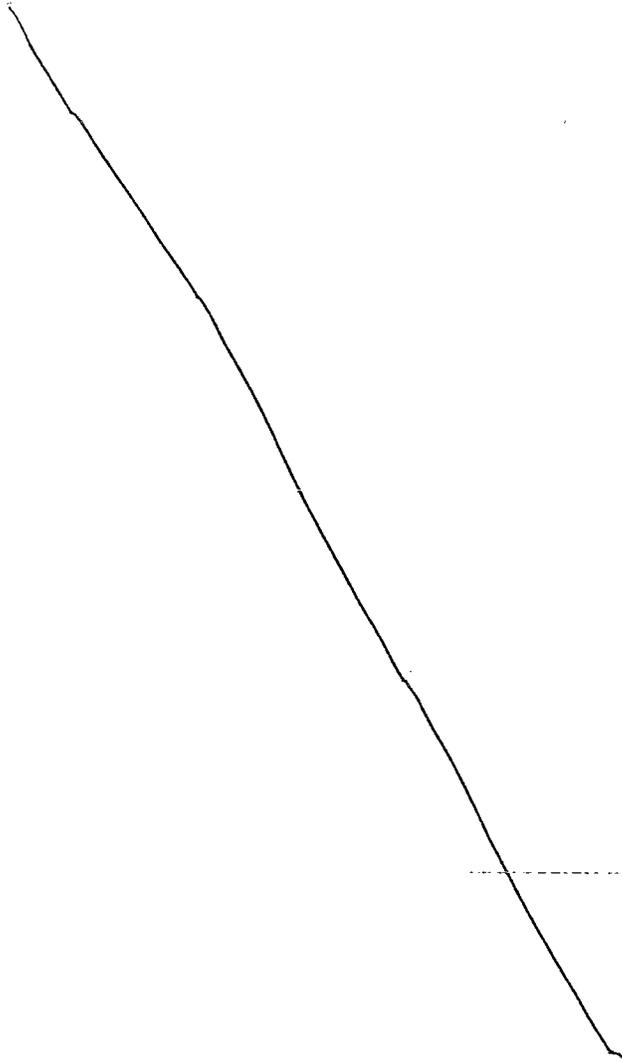
- We realize that much of this label will be "class labeling" for the topical corticosteroids. Please consider if each label should talk broadly about the class risks or if it should name the specific product. For example, should we say that "Topical corticosteroids can cause HPA axis suppression" or "Topical corticosteroids, including Locoid Lotion, can cause HPA axis suppression, or "Locoid Lotion can cause HPA axis suppression"? The second version is similar to class labeling wording used for fluoroquinolone antibiotic labels. Please consider how to word these discussions both in Highlights and in the Full Prescribing Information (FPI).
- We note that the Pregnancy section for this label is unusually long. While there is no recommendation on how long this section can or should be, please consider if all the information presented here is truly relevant to the prescriber. Overloading the section with too much information can actually dilute the important messages.
- We note that this label does not include a section for "10 Overdosage." Although this section is optional and does not appear in all labels, please consider if it should be added here. If so, it could include a broad, brief discussion of the risks of overdose with this product and any necessary cross-references to similar discussions elsewhere in the label. Please also consider if this should be included in "class labeling" for these products.

HIGHLIGHTS

- *“These highlights do not include all the information needed to use Locoid Lotion safely and effectively. See full prescribing information for Locoid Lotion.”*

The preferred formatting for these statements is to use bolded type.

Indications and Usage



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4 Page(s) Withheld

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x Draft Labeling (b4)

 Draft Labeling (b5)

 Deliberative Process (b5)

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/s/

Iris Masucci
5/1/2007 02:48:26 PM
DDMAC REVIEWER

Laurie Burke
5/1/2007 06:23:12 PM
INTERDISCIPLINARY

Study Endpoints and Label Development (SEALD) Team Review of PLR Labeling

Application Number: NDA 22-076

Applicant: Ferndale Labs

Drug Names: Locoid (hydrocortisone butyrate) Lotion

Receipt Date: August 18, 2006

SEALD Review Date: December 7, 2006

Project Manager: Melinda Bauerlien

Review Division: Division of Dermatology and Dental Products

SEALD Reviewer(s): Jeanne M. Delasko, RN, MS/Label Initiatives Specialist

Concurrence(s): Laurie B. Burke, RPh, MPH/Director, SEALD

Executive Summary

This memo provides a list of revisions for the proposed labeling that should be conveyed to the applicant. These comments are based on Title 21 of the Code of Federal Regulations (201.56 and 201.57), the preamble to the Final Rule, Guidance(s), and FDA recommendations to provide for labeling quality and consistency across review divisions. When a reference is not cited, consider these comments as recommendations only.

SEALD Comments

Highlights:

- Because the drug names, dosage form, and route of administration appear at the beginning of the labeling, product identification information [i.e., LOCOID (hydrocortisone butyrate) Lotion, 0.1%] is not needed as a header in Highlights and should be deleted. However, the proprietary and established names can be repeated at the beginning of the FPI, or at the beginning of each page of the FPI (e.g., as a header), if this enhances product identification on subsequent pages of the labeling. [See Implementation Guidance (Frequently Asked Question #4)]
- The revision date will be the month/year that the supplement is approved, not 08/2006.

Full Prescribing Information (FPI): Contents:

- Section 10 must read OVERDOSAGE, not OVERDOSE. Please correct in Table of Contents and FPI. [See 21 CFR 201.56(d)(1)]

- Section 13 must read NONCLINICAL TOXICOLOGY, not NONCLINICAL TOXICOLOGY SECTION. Please correct in Table of Contents and FPI. [See 21 CFR 201.56(d)(1)]

Full Prescribing Information:

- Indent all paragraphs, headings, subheadings throughout the FPI. For overall FPI formatting, refer to <http://www.fda.gov/cder/regulatory/physLabel/default.htm> for fictitious examples of labeling in the new format.
- The preferred presentation of cross-references in the FPI is the section (not subsection) heading followed by the numerical identifier. For example, [*see Use in Specific Populations (8.4)*], not [see Use in Specific Populations – Pediatric Use (8.4)]. The cross-reference should be in brackets. Because cross-references are embedded in the text in the FPI, the use of italics to achieve emphasis is encouraged. Please fix all cross-references throughout the labeling. [See Implementation Guidance]
- You refer to adverse reactions as “adverse events” or “drug-related adverse events.” Please refer to the “Guidance for Industry: Adverse Reactions Sections of Labeling for Human Prescription Drug and Biological Products – Content and Format,” available at <http://www.fda.gov/cder/guidance> and revise your Adverse Reactions section accordingly.
- Under Patient Counseling Information, use command language. For example, use “Report signs” instead of “Patients *should* report signs.” Also, there are no subsection headings. However, you have numbered each item (i.e., 17.1 through 17.7). Delete the numbers. Bullet each item.
- The manufacturer information is missing and must be located after Patient Counseling Information section, at the end of the labeling. [See 21 CFR 201.1]
- Delete “Revised: 08/2006” at the end of the labeling. The revision date at the end of Highlights replaces this information.

Recommendations

After the comments are conveyed to the applicant and revised labeling is submitted, please check to ensure that SEALD labeling comments have been addressed and incorporated into the labeling. At the first labeling meeting, use the applicant’s updated (revised) draft labeling for review.

Appendix A: Applicant’s Proposed Labeling

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X Draft Labeling (b4)

 Draft Labeling (b5)

 Deliberative Process (b5)

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/s/

Jeanne Delasko
12/12/2006 10:38:37 AM
CSO

Laurie Burke
12/12/2006 11:24:46 AM
INTERDISCIPLINARY