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APPLICATION NUMBER:

22-102

OTHER REVIEW(S)

Division of Metabolism and Endocrinology Products (DMEP)

**REGULATORY PROJECT MANAGER LABELING FORMAT REVIEW
(PHYSICIAN LABELING RULE)**

Application Number: NDA 22-102

Name of Drug: cyanocobalamin, USP Nasal Spray, 25 mcg/0.1 mL

Applicant: Fleming & Company, Pharmaceuticals

Submission Date: January 22, 2007

Receipt Date: January 23, 2007

DMEP Review Date: June 25, 2007

Project Manager: Jennifer Johnson

CPMS Concurrence: Lina AlJuburi

Executive Summary

This review provides a list of format revisions for the proposed labeling (Word) 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.

DMEP Comments

Highlights

1 Page(s) Withheld

 Trade Secret / Confidential (b4)

 ✓ Draft Labeling (b4)

 Draft Labeling (b5)

 Deliberative Process (b5)

Recommendations

After the comments are conveyed to the applicant and revised labeling is submitted, comments will be checked to ensure that all have been addressed and incorporated into the labeling. At the first labeling meeting scheduled for Friday, July 6, 2007, the applicant's updated (revised) draft labeling will be used for review.

Appendix A: Applicant's Proposed Labeling

Attached product labeling.

Drafted: J.Johnson/06.25.07

Revised/Initialed: L.AJuburi/06.29.07

Finalized: J.Johnson/07.01.07

Filename: CSO Labeling Review Template (updated 1-16-07).doc

CSO LABELING REVIEW OF PLR FORMAT

APPEARS THIS WAY ON ORIGINAL

APPEARS THIS WAY ON ORIGINAL

16 Page(s) Withheld

 Trade Secret / Confidential (b4)

✓ Draft Labeling (b4)

 Draft Labeling (b5)

 Deliberative Process (b5)

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/s/

Jeanine Best
5/25/2007 02:08:18 PM
DRUG SAFETY OFFICE REVIEWER

Toni Piazza Hepp
5/25/2007 06:22:28 PM
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