CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-841

CSO LABELING REVIEW(S)

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 75-841 **Date of Submission: February 28, 2000**
Applicant's Name: Whitney Pharmaceuticals, Inc.
Established Name: Pamidronate Disodium Injection, 3 mg/mL, 6 mg/mL, and 9 mg/mL

Labeling Deficiencies:

1. GENERAL COMMENTS: Please differentiate between multiple product strengths using different colors, as does the reference listed drug. Currently it appears that all three strengths of your product are shaded with the same color.

2. CONTAINER (10 mL) – See GENERAL COMMENTS.
3. CARTON (1 x 10 mL) – See GENERAL COMMENTS.
4. INSERT - **Please make the revisions in the mocked up copy of your insert**

Please revise your labels and labeling, as instructed above, and submit 12 copies of final printed labels and labeling.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes- http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

Wm. Peter Rickman,
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

SEP 18 2001

REVIEW OF PROFESSIONAL LABELING #2
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 75-841 Date of Submission: April 6, 2001
Applicant's Name: Whitney Pharmaceuticals, Inc.
Established Name: Pamidronate Disodium Injection, 3 mg/mL, 6 mg/mL, and 9 mg/mL, 10 ml vials.

Labeling Deficiencies:

1. GENERAL COMMENTS: We again ask that you further differentiate between your three product strengths. Currently it appears that the declaration of all three strengths of your product are shaded with the same color. Please differentiate between multiple product strengths using different colors, as does the reference listed drug. We suggest color coding the strengths (i.e. 60 mg/10mL) rather Just 60 mg and the product name. We note that the color used on the 30 mg and 60 mg products are difficult to distinguish the color difference.
2. CONTAINER (10 mL) – See GENERAL COMMENTS.
3. CARTON (1 x 10 mL) – See GENERAL COMMENTS.
4. INSERT
   a. DESCRIPTION – You must state that your product is a "sterile" product.
   b. 3rd sentence revise as follows: Each mL of the 30 mg vial contains : 3 mg Pamidronte Disodium; 47 mg Mannitol, USP; Water for Injection, USP, q.s.;Phosphoric acid to adjust pH. Each mL of the 60 mg vial contains.... Each mL of the 90 mg vial contains...The pH of a 1% solution...

Please revise your labels and labeling, as instructed above, and submit 12 copies of final printed labels and labeling.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes- http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

Wm. Peter Rickman,
Acting Director
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