

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-915

APPROVABLE LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

AE Letter 2/1/2006

NDA 21-915

Baxter Healthcare Corporation
Attention: Vicki Drews, Associate Director, Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, Illinois 60085

Dear Ms. Drews:

Please refer to your new drug application dated March 30, 2005, received April 1, 2005, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Ondansetron Injection, USP, premix in IntraVia Plastic Container, 8 mg/50 mL and 32 mg/50 mL in Iso-osmotic Sodium Chloride solution.

We acknowledge receipt of your submissions dated May 20 and 31, June 30, November 23, December 12, 14, 22, 2005, as well as your submissions dated January 20, 23, 30, and 31, 2006.

We also refer to our January 19 and 24, 2006 teleconferences between the Division and Baxter Healthcare Corporation representatives to discuss issues regarding your proposed label.

We also refer to our January 30, 2006 teleconference between Dr. Steven Caffé, Baxter Senior Vice President of Regulatory Affairs and the Division to further discuss issues regarding the approvability of your proposed Ondansetron Injection, USP, premix in IntraVia Plastic Container, 8 mg/50 mL in Iso-osmotic Sodium Chloride solution.

We completed our review of this application, as amended, and it is approvable. Before the application may be approved, however, it will be necessary for you to do the following:

Conduct a prospective, randomized, double-blind clinical trial designed to demonstrate efficacy for your proposed 8 mg once daily dose.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

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Under 21 CFR 314.102(d), you may request an informal meeting or telephone conference with this Division to discuss what steps need to be taken before the application may be approved.

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

If you have any questions, call Betsy Scroggs, Regulatory Project Manager, at (301) 769-0991.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Joyce Korvick
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NDA 21-915

Baxter Healthcare Corporation
Attention: Vicki Drews, Associate Director, Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, Illinois 60085

Dear Ms. Drews:

Please refer to your new drug application dated March 30, 2005, received April 1, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ondansetron Injection, USP, 8 mg/50 mL iso-osmotic sodium chloride solution and 32 mg/50 mL iso-osmotic sodium chloride solution PreMix in INTRAVIA Plastic Container.

We acknowledge receipt of your submissions dated March 27, April 13, and April 14, 2006.

Your submission of March 27, 2006 constituted a complete response to our February 1, 2006 action letter and provides to revise your label to include the indication for your 32 mg/50 mL PreMix only.

This NDA provides for the use of Ondansetron Injection, USP, 32 mg/50 mL PreMix in the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including high-dose cisplatin. Efficacy of the 32 mg single dose beyond 24 hours in these patients has not been established.

We completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed upon enclosed labeling text submitted April 14, 2006 and for the immediate container, overwrap, and carton labels submitted January 30, 2006. This determination is contingent upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in manufacturing and testing of the drug product) and is, therefore, subject to change on the basis of any new information that may come to our attention.

The listed reference drug product upon which you base your application is subject to a period of patent protection and exclusivity protection and therefore, final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] may not be made effective until the period has expired, i.e., December 24, 2006.

At least 90 days prior to December 24, 2006 or when requested, submit an amendment to this application identifying changes, if any, in the conditions under which your product was tentatively approved. This information should include updated labeling, chemistry, manufacturing and controls data, and a safety update.

Failure to submit this amendment will prompt a review of the application that may result in rescission of the tentative approval letter.

Any significant change in the conditions outlined in this NDA requires our review before final approval may be granted.

Before we issue a final approval letter, this NDA is not deemed approved. If you believe that there are grounds for issuing the final approval letter before December 24, 2006, you should amend your application accordingly.

This product may be considered misbranded under the Federal Food, Drug, and Cosmetic Act if it is marketed with this change before final approval.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred.

We acknowledge your May 20, 2005 amendment containing your request for a waiver in pediatric patients.

The current application provides solely for the use of Ondansetron Injection, USP, 32 mg/50 mL PreMix in the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including high-dose cisplatin. Additionally, since the current application no longer provides for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens; the Pediatric Research Equity Act (PREA) does not apply to this application.

If you have any questions, call Betsy Scroggs, Regulatory Health Project Manager, at (301) 796-0991.

Sincerely,

(See appended electronic signature page)

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

Joyce Korvick
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