

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-915

APPROVAL LETTER



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, 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, 14, October 26, and November 10, 2006.

Your March 27, 2006 submission constituted a complete response to our February 1, 2006 action letter.

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 in adult patients, 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 approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert, immediate container and carton labels submitted October 26, 2006). As discussed in our December 26th and 27th teleconference, you agreed to make the following revisions at the next printing:

1. Package insert:

- a. In the **DESCRIPTION** section please add the following line as seen in the reference listed drug (RLD):
 - i. **Sterile, Premixed Solution for Intravenous Administration in Single-Dose, Flexible Plastic Containers.**
- b. Please remove the word ZOFTRAN throughout the label and replace appropriately with ondansetron.
- c. In your Table headings please include the words "in Adult(s)" or "Adult(s)" where appropriate.

- d. In the **INDICATIONS AND USAGE** section please add the words “in adult patients” in the first sentence after cancer chemotherapy to read:
 - i. Prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy in adult patients, including high-dose cisplatin.

- e. In the **DOSAGE AND ADMINISTRATION** section under the Pediatric Use subsection please revise the paragraph to read:
 - i. The ondansetron premixed formulation is not recommended for use in children. The ondansetron premixed formulation is a fixed dosage form that has not been studied in the pediatric population, and is not appropriate for weight based dosing in pediatric patients.

2. Overpouch Labeling:

- a. Please bold and capitalize the words **RECOMMENDED STORAGE**.

These revisions are terms of the NDA approval.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate this submission “**FPL for approved NDA 21-915.**” Approval of this submission by FDA is not required before the labeling is used.

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 are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Gastroenterology Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Giuseppe Randazzo, Regulatory Project Manager, at (301) 796-0980.

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

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

/s/

Joyce Korvick
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