



NDA 8-678/S-025 and S-026

Sandoz Inc.
Attention: Bruce Suknanan
Regulatory Affairs Associate
227-15 North Conduit Avenue
Laurelton, New York 11413

Dear Mr. Bruce Suknanan:

Please refer to the following supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Isoniazid Tablets, 100mg and 300mg:

Supplement Number	Submission Date	Receipt Date
S-025	October 5, 2006	October 24, 2006
S-026	February 1, 2007	March 7, 2007

These “Changes Being Effected” supplemental new drug applications provide for the following changes:

S-025 Structured Product Labeling (SPL)

S-026 Addition of text to the **PRECAUTIONS/Drug Interactions**/Food subsection of the package insert submitted in response to the Division’s supplement request letter dated November 9, 2006. The revisions are as follows (added text is underlined).

Isoniazid should not be administered with food. Studies have shown that the bioavailability of isoniazid is reduced significantly when administered with food. Tyramine-and histamine-containing foods should be avoided in patients receiving isoniazid. Because isoniazid has some monoamine oxidase inhibiting activity, an interaction with tyramine-containing foods (cheese, red wine) may occur. Diamine oxidase may also be inhibited, causing exaggerated response (e.g., headache, sweating, palpitations, flushing, hypotension) to foods containing histamine (e.g., skipjack, tuna, other tropical fish).

It is noted that the word “oxidase” has been misspelled in the February 1, 2007 submission. Please correct this error at the package insert’s next printing.

We have completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text submitted February 1, 2007.

If you have any questions, please call Christine Lincoln, RN, M.S., MBA, Regulatory Health Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Steve Gitterman, M.D., Ph.D.
Deputy Director for
Renata Albrecht, M.D.
Director
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Office Antimicrobial Products
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/s/

Steven Gitterman
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