DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-657/S-026, S-027

Pfizer, Inc.
Attention: Pritpal Nijjar
Regulatory Manager
235 East 42nd St.
New York, NY 10017

Dear Ms. Nijjar:

Please refer to your supplemental new drug applications dated January 7, 2004, received January 8, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FLAGYL® I.V. RTU® (metronidazole injection, USP).

We acknowledge receipt of your submission dated February 25, 2004.

These "Changes Being Effected" supplemental new drug applications provide for revised labeling to comply with the Final Rule entitled "**Labeling Requirements for Systemic Antimicrobial Drug Products Intended for Human Use"** (68FR 6062, February 6, 2003) and respond to our CBE request letter dated September 11, 2003. Microbiology and chemistry-related labeling changes were also made to the package insert.

These "Changes Being Effected" supplemental new drug applications provide for the following additions to the package insert:

Location	**Added text**	**Change Acceptable**
At the beginning of the label, under "**PRODUCT NAME"**	To reduce the development of drug-resistant bacteria and maintain the effectiveness of and other antibacterial drugs, Metronidazole Injection, USP RTU® should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	yes
DESCRIPTION	Updated chemical structure and substitution of "safety" for "suitability".	yes
CLINICAL PHARMACOLOGY section under *Susceptibility Tests*	Updated information regarding organisms susceptible to metronidazole and the MIC for the strains.	yes
INDICATIONS AND USAGE	To reduce the development of drug-resistant bacteria and maintain the effectiveness of Metronidazole Injection, USP RTU® and other	yes

	antibacterial drugs, Metronidazole Injection, USP RTU® should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.	
PRECAUTIONS section, under "General" subsection	Prescribing Metronidazole Injection, USP RTU® in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication it is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.	yes
PRECAUTIONS section, under "Information for patients"	Patients should be counseled that antibacterial drugs including Metronidazole Injection, USP RTU® should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When Metronidazole Injection, USP RTU® is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not competing the full courses of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by Metronidazole Injection, USP RTU® or other antibacterial drugs in the future.	yes
DOSAGE AND ADMINISTRATION	Information regarding the inspection of the physical appearance of parenteral drug product.	yes
REFERENCES	Updated trademark information and minor editorial changes.	yes

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed label submitted on January 7, 2004 (enclosed). Accordingly, this supplemental application is approved effective on the date of this letter.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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

If you have any questions, call Robin Anderson, R.N., M.B.A., Labeling Reviewer at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
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/

Renata Albrecht
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