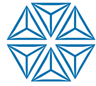

Bristol-Myers Squibb Company

U.S. Medicines Group

P.O. Box 4500 Princeton, NJ 08543-4500

December 9, 2002

IMMEDIATE ATTENTION REQUIRED
DISPENSING ERROR ALERT

Dear Health Care Provider,

Bristol-Myers Squibb and AstraZeneca have received reports of prescription dispensing errors involving **SERZONE® (nefazodone HCl) Tablets** and **SEROQUEL® (quetiapine fumarate) Tablets**.

According to the medication error reports, verbal and written prescriptions were incorrectly interpreted, labeled, and/or filled due to the similar names between **SERZONE** and **SEROQUEL**. Furthermore, the overlapping strengths (100 mg and 200 mg), the dosage form (tablets), the dosing interval (BID), and the fact that these two products are stocked close together in pharmacies were also critical in causing medication errors. Additionally, both drugs are generally titrated in similar increments to overlapping target ranges (see prescribing information).

The error reports involve dispensing **SERZONE** Tablets when **SEROQUEL** Tablets were prescribed and the reverse scenario. Patients erroneously receiving either medication would be inadequately treated; control of schizophrenia symptoms may deteriorate in patients erroneously receiving **SERZONE**, while depression may worsen in patients inappropriately receiving **SEROQUEL**. In addition, patients may be placed at risk for adverse events.

SERZONE is an antidepressant drug marketed as ***hexagonal*** tablets imprinted with "BMS" and the strength on one side and the identification code number on the other. The 100 mg (white) and 150 mg (peach) tablets are bisect scored on both tablet faces; the 50 mg (light pink), 200 mg (light yellow), and 250 mg (white) tablets are not scored.

SEROQUEL is an antipsychotic drug marketed as ***round***, biconvex film coated tablets identified with "SEROQUEL" and the strength on one side and plain on the other. The 25 mg tablets are peach-colored, the 100 mg tablets are yellow, and the 200 mg tablets are white.

Bristol-Myers Squibb has developed a patient-information leaflet about **SERZONE**, which is being given to patients when prescriptions are filled. These leaflets will facilitate communication between you and your patients and help ensure that patients receive the correct medication. Please encourage your patients to make sure that the medication dispensed by the pharmacist matches the **SERZONE** picture card enclosed with this letter and the description of **SERZONE** tablets in the patient-information leaflet. Also, encourage your patients to be certain that the tablets they receive are imprinted with "BMS".

Additionally, certain packaging changes to both products have been implemented that highlight the endings of the product names. The revised **SERZONE (nefazodone HCl)** logo appears at the end of this letter. This should assist the dispenser in distinguishing the products.

Recommended actions to help prevent dispensing errors

If you become aware of a prescription dispensing error involving **SERZONE** or **SEROQUEL**, please contact one of the following:

❖ USP Medication Errors Reporting Program (1-800-233-7767 or www.usp.org)

❖ Institute for Safe Medicines Practice (www.ismp.org)

❖ FDA MEDWATCH program (phone 1-800-FDA-1088, FAX 1-800-FDA-0178, Internet: www.fda.gov/medwatch or www.fda.gov/medwatch, or mail: FDA Safety Information and Adverse Event Reporting Program, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787)

❖ Bristol-Myers Squibb Company at 1 (609) 818-3737 [**SERZONE**]

❖ AstraZeneca at 1 (800) 236-9933 [**SEROQUEL**]

For additional information please contact:

❖ Bristol-Myers Squibb Drug Information Department at 1 (800) 321-1335

❖ AstraZeneca Information Center at 1 (800) 236-9933

Thank you.

Sincerely,

Darlene Jody, M.D.
Vice President Global Medical Marketing
Bristol-Myers Squibb Company

PLEASE CONSULT THE ENCLOSED COMPLETE PRESCRIBING INFORMATION FOR **SERZONE**, INCLUDING **BOXED WARNING REGARDING HEPATOTOXICITY**.

serZONE®
(nefazodone HCl)

D5-D0071