June 20, 2001

Phar-Mor, Inc., Store #124
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Dockets Management Branch
Food & Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

To Whom It May Concern,

We are formally petitioning Novartis in regards to the labeling of your product, Clozaril. As pharmacists, we are extremely concerned about the Clozaril product labeling. In reading the package insert, as well as the product label, in their entirety, there is no reference to the extent of pharmacy involvement in the dispensing of Clozaril. In the warning box of the package insert, a suggestion is made that this medication is "*available only through a **distribution system** that ensures monitoring of WBC counts.*" This does not, however, accurately specify the extent of involvement of the pharmacist in this process. There is absolutely no mention of the fact that pharmacists must be enrolled in the Clozaril National Registry, nor is there any mention that pharmacists must actually see the results of the WBC counts.

According to the wording of the package insert, it is interpreted to be the responsibility of the doctor to ensure the proper distribution of Clozaril. Due to vague product labeling, our concern as pharmacists is that if the doctor does not direct the patient to a registered pharmacy, along with a WBC count and a prescription written for a week supply, then the pharmacy may not be alerted to the rules and regulations regarding Clozaril. Only twice is the Clozaril National Registry even mentioned, once in the black box warning under agranulocytosis and once in the precautions profile under pulmonary embolism. However, it appears to be referred to as a source of information from a drug study, rather than an enrollment requirement for the pharmacy.

The warning in the package insert and on the bottle itself specifically states, "*It is **recommended** that drug dispensing should not **ordinarily** exceed a weekly supply. If a patient is eligible for WBC testing every other week, then a two week supply of CLOZARIL (clozapine) can be dispensed. Dispensing **should be contingent upon** the results of a WBC count.*" This statement does not convey to pharmacists their responsibilities. Using the words "recommended," "ordinarily," and "should be contingent upon" are only suggestive, not requirements.

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Our recommendation on how to educate and inform pharmacists on these requirements would be to change the wording on the package insert & the product labeling. On the

product itself, the warning should read "**ATTENTION PHARMACIST: Pharmacy must be enrolled in Clozaril National Registry in order to dispense this product. Product should not be dispensed without reviewing a satisfactory WBC and should not exceed a 7 day supply within the first six months of treatment. See package insert.**" It would also be helpful if there were a notation on the front of the bottle specifying "**See Warnings.**" This same statement should also be included in the package insert at the beginning of the Warnings section along with the phone number to the Clozaril National Registry.

We, as concerned pharmacists, want to prevent any future dispensing of Clozaril without following proper procedures, due to the potential harm to the patient. We appreciate your attention to this matter. If you have any questions, you can contact us at the above address or phone number.

Sincerely,

Anita Lindsay, PharmD

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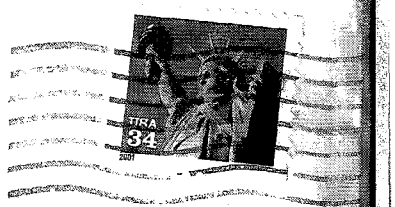

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