

August 2, 2002

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

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PETITION FOR STAY OF ACTION

Bayer HealthCare, Consumer Care Division submits this petition under 21 CFR § 10.35 to request that the Commissioner of Food and Drugs stay the effective date of compliance for the monograph title change for active hydroxypropyl methylcellulose to hypromellose. The change indicates that all labeling must reflect this name change by September 1, 2002. Bayer HealthCare, Consumer Care Division is requesting an extension of this date. With additional time, Bayer will be able to incorporate the name change during future manufacturing runs.

A. Decision Involved.

In the May-June 2000 edition of the Pharmacopeial Forum a proposal was published to change the monograph name of hydroxypropyl methylcellulose to hypromellose. This name change has been adopted by the US Pharmacopeia (USP) to harmonize with the terminology recommended by the World Health Organization (WHO) committee. It is also currently being used in the European Pharmacopoeia. The official effective date is September 1, 2002. Bayer HealthCare has been preparing to make the necessary changes but discovered delays in receiving revised product specifications from raw material vendors.

B. Action Requested.

Bayer HealthCare requests that FDA extend the September 1, 2002 official date for one year to name change hydroxypropyl methylcellulose to hypromellose. The extension will allow Bayer to use up its current supply of product labeling and have enough time to acquire proper documents from our suppliers such as reference to literature, MSD Sheets, specifications, etc.

C. Statement of Grounds.

21 CFR § 10.35(e) states that the Commissioner shall grant a stay in any proceeding if all of the following apply:

- (1) the petitioner will otherwise suffer irreparable injury;
- (2) the petitioner's case is not frivolous and is being pursued in good faith;
- (3) the petition has demonstrated sound public policy grounds supporting the stay; and
- (4) the delay resulting from the stay is not outweighed by public health or other public interests.

Bayer believes that each of these criteria apply to our situation. This change has required extensive efforts to review, establish, and coordinate compliance procedures between various companies. The change affects at least one sku of each Bayer brand sold in consumer care. To discard current inventory of product labeling will be very costly from an inventory and sales position. Bayer will incur this cost plus any loss of sales if product can not be marketed without this change after September 1, 2002.

Bayer's petition is not frivolous and is being pursued in good faith. Bayer had begun to comply with the final rule in-house but due to the delay with our vendors have found it nearly impossible to meet the due date. The Pharmacopeial Forum (PF) stated that the decision was made to adopt the European convention for nomenclature regarding hydroxypropyl methylcellulose to hypromellose, a term used for several years.

There are no countervailing public health concerns that exist with the denial of this stay. There is also no public health risk allowing Bayer a limited period of extension. This change has no impact on the integrity of Bayer products as they continue to meet all other USP requirements. Allowing Bayer sufficient time to complete a normal manufacturing cycle will avoid economical stress of product labeling and manpower.

D. Conclusion.

For the reasons listed above, Bayer request the stay of action be granted. If there are any questions or should you need further assistance please contact me at (973) 408-8093. In my absence please contact MaryRose Salvacion at (973) 254-4675.

Sincerely,
Bayer Corporation, Consumer Care Divison


for Joanne Robinett
Director, Regulatory Affairs

cc: File