



Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

JAN 24 2001

Re: **Docket No. 99N-3088**
RIN 0910-AB33
Marketing Exclusivity and Patent Provisions for Certain Antibiotic Drugs

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Dear Sir or Madam:

Reference is made to the FDA's proposed rule published in the Federal Register of January 24, 2000, to exempt marketing applications for certain antibiotic drug products from the regulatory provisions governing marketing exclusivity. The proposal would apply to marketing applications for drug products containing an antibiotic drug that was subject of a marketing application received by the FDA before November 21, 1997, the effective date of the Food and Drug Administration Modernization Act of 1997.

Reference is also made to a January 22, 2001 telephone conversation between the FDA's Mr. Wayne Mitchell and the undersigned regarding a submission that AstraZeneca made to the FDA's Division of Anti-Infective Drug Products on January 22, 1999. In that submission, AstraZeneca Pharmaceuticals LP indicated that our drug product, MERREM[®] I.V. (meropenem for injection), NDA No. 50-706, should be classified as an "anti-infective" and not an antibiotic as defined previously by Section 507 [357](a) of the Federal Food, Drug and Cosmetic Act. Mr. Mitchell indicated that FDA is in the process of finalizing the proposed rule, and he requested that AstraZeneca submit a copy of our January 22, 1999 document to the above-referenced Docket for consideration as soon as possible.

Accordingly, attached is a copy of our January 22, 1999 submission to the FDA's Division of Anti-Infective Drug Products regarding the classification of MERREM[®] I.V. As noted in the document cover letter, microorganisms do not produce the structural component of the active ingredient of MERREM[®] I.V. that imparts the capacity to inhibit or destroy microorganisms. The synthesis of meropenem, and all intermediates in the synthetic pathway, cannot be manufactured by fermentation and is described in the MERREM[®] I.V., NDA No. 50-706 and in Sumitomo's DMF #10322. The January 22, 1999 submission also provided a review article by S. Coulton and E. Hunt (Progress in Medicinal Chemistry 1996; 33:99-145) that discusses the chemistry and biology of carbapenems. In this article, meropenem is characterized as a totally synthetic non-natural carbapenem, providing further evidence that MERREM[®] I.V. does not meet the strict definition of an antibiotic.

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