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MERCK
Research Laboratories

Docket No. 99N-3088
Marketing Exclusivity and Patent Provisions for Certain Antibiotic Drugs

Merck & Co., Inc. is a leading worldwide, human health product company. Merck's corporate strategy -- to discover new medicines through breakthrough research -- encourages us to spend more than $2 Billion annually on worldwide Research and Development (R & D). Through a combination of the best science and state-of-the-art medicine, Merck's R & D pipeline has produced many of the important pharmaceutical products on the market today.

Merck supports regulatory oversight of product development that is based on sound scientific principles and good medical judgment. Regulators must be reasonable, unbiased and efficient when they review the quality, effectiveness and safety of our products. It is in both of our interests to see that important therapeutic advances reach patients without unnecessary or unusual delays.

Among Merck's human health products is Primaxin, a leading wide-spectrum antibiotic. For this reason, we are very interested in and well qualified to comment on this Draft FDA guidance to provide Marketing Exclusivity and Patent Provisions for Certain Antibiotic Drugs.

Merck strongly disagrees with FDA's proposed reliance on a comparison of "active moieties" to determine whether a drug that is the subject of a post-FDAMA NDA contains a pre-repeal antibiotic drug and is therefore to be exempted from the marketing exclusivity and patent provisions of section 505 of the Act. Merck's position on this issue is in agreement with that of PhRMA.

The FDA's Hatch-Waxman Act exclusivity regulations define "active moiety" to include non-covalent salts and covalent ester derivatives of the "active moiety". Merck is hereby requesting that the FDA in its final rule for marketing exclusivity and patent provisions for antibiotic drugs provide clarification that a covalent derivative of a pre-repeal antibiotic drug (other than an ester) that requires metabolic conversion to generate the pre-repeal "active moiety" will be considered a "New Chemical Entity" and thus be entitled to the marketing exclusivity provisions of sections 505(c)(3)(D)(ii) and 505(j)(5)(D)(ii) of the Act. The Hatch-Waxman exclusivity regulations for non-antibiotic

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drugs have considered such metabolically-converted compounds to be "new chemical entities" entitled to 5-years of exclusivity [see 59 Fed. Reg. 50338 (October 3, 1994)]. Merck is requesting a consistent interpretation by the FDA of the term "active moiety" for both antibiotic and non-antibiotic drugs such that a compound (other than an ester) that requires metabolic conversion to produce an already approved active moiety will be considered a "new chemical entity" entitled to 5 years of exclusivity under sections 505(c)(3)(ii) and 505(j)(5)(D)(ii) of the Act.

We appreciate the opportunity to provide comments which, from our perspective, will clarify some of the outstanding issues. We trust that these comments will be considered in further development of the proposed rule.

Sincerely,

Dennis M. Erb

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