Aventis Pharmaceuticals

Aventis



February 23, 2001

Via fax and UPS

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 00N-1595
Draft Guidance for Industry on Recommendations for Complying With the Pediatric Rule; Availability; 65 Fed Reg 75720 (Dec.4, 2000)

Dear Sir/Madam:

Aventis Pharmaceuticals is pleased to provide the following comments on the above-referenced draft guidance for industry entitled, "Recommendations for Complying With the Pediatric Rule (21 CFR 314.55(a) and 601.27 (a))". The draft guidance provides recommendations for sponsors of new drug applications (NDA's) and biologics license applications (BLA's) on how to meet the requirements of the final rule requiring manufacturers to assess the safety and effectiveness of new drugs and biological products in pediatric patients (pediatric rule).

While we are in general agreement with the FDA recommendations given in the draft, we offer the following comment for your consideration.

**VI. COMPLIANCE WITH THE PEDIATRIC RULE-WHAT HAPPENS IF I DON'T DO A PEDIATRIC ASSESSMENT?**

"If pediatric studies to evaluate safety and effectiveness are not submitted by a manufacturer in the time allowed, the drug product may be considered misbranded or an unapproved new drug or unlicensed biologic (21 CFR 201.23(d)). When a product is misbranded or an unapproved new drug, sections 302, 303, and 304 of the Act (21 U.S.C. 332, 333, 334) authorize injunction, prosecution, or seizure. The Agency can also seek an injunction or bring prosecution under the Public Health Service Act. FDA can bring an enforcement action for injunctive relief for failure to submit a required assessment of pediatric safety or effectiveness. Violation of the injunction could result in a contempt proceeding or such other penalties as a court orders (e.g., fines)."

Aventis considers the consequences of misbranding or designation as an unapproved new drug or unlicensed biologic too drastic a measure by the FDA if

00N-1595 C1

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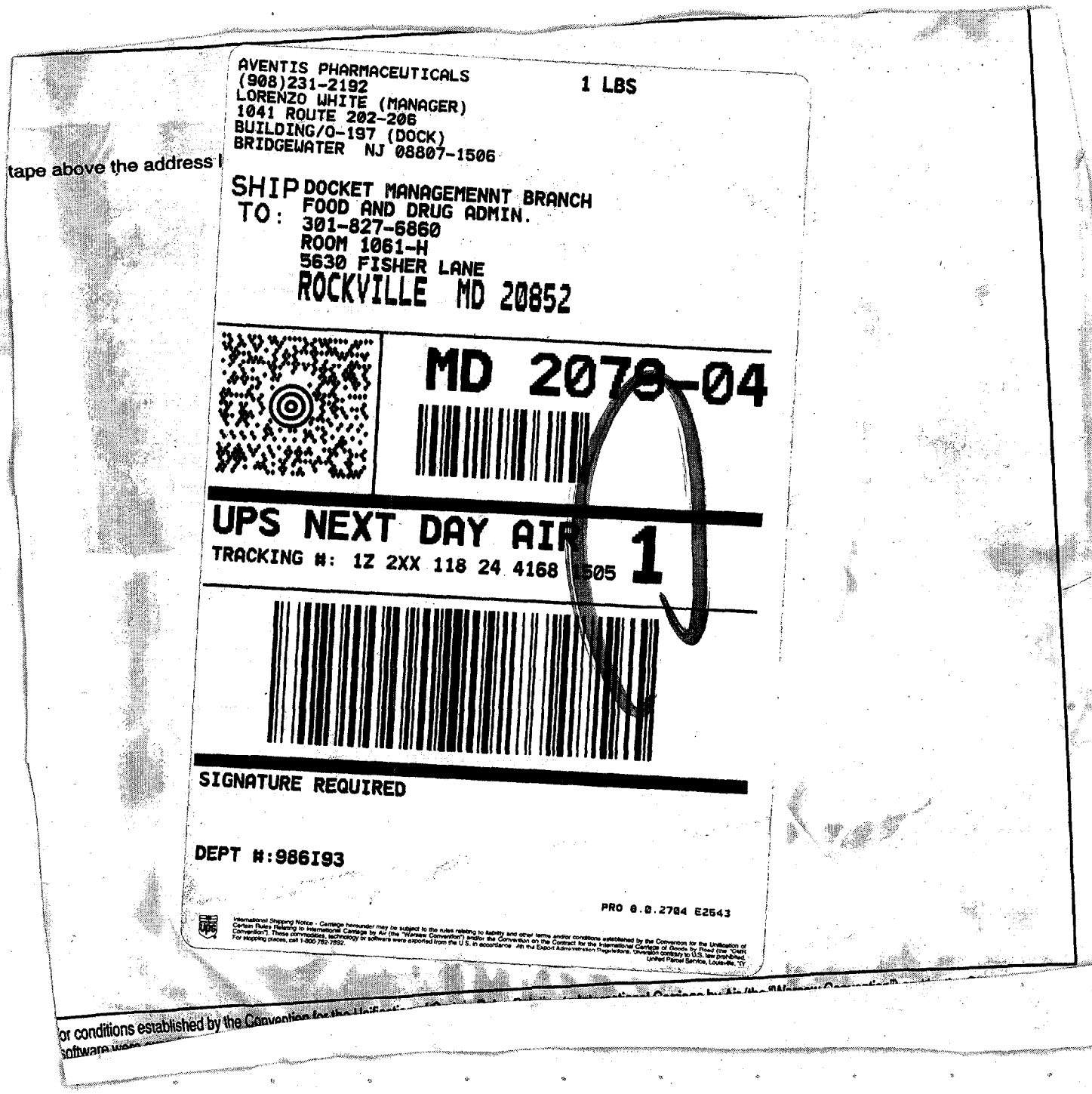
the sponsor fails to submit a pediatric assessment. Instead, the Agency should emphasize that if the sponsor did not show due diligence in trying to conduct pediatric studies, then the Agency could take some action to require such studies or restrict the drug product to the non-pediatric population. However, the drug product should not be considered "misbranded" or an unapproved new drug or an unlicensed biologic resulting in injunction, prosecution or seizure, thus depriving other patient populations of therapy.

Thank you for your consideration.

Sincerely,

James Boyd, Ph.D., MBA
N.A. Regulatory Center Head
Global Drug Regulatory Affairs



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