



DEPARTMENT OF HEALTH & HUMAN SERVICES

JAN 30 2007

Food and Drug Administration
Rockville MD 20857

4010 7 FEB -1 19:43
The Honorable James H. Douglas
Governor, State of Vermont

The Honorable Jim Doyle
Governor, State of Wisconsin

The Honorable Tim Pawlenty
Governor, State of Minnesota

The Honorable Kathleen Sebelius
Governor, State of Kansas

c/o Jason D. Rohloff
Director of Federal Affairs
Office of Governor Tim Pawlenty
400 North Capitol Street, Suite 380
Washington, D.C. 20001

Re: Docket No. 2006P-0306/CP1

Dear Governors Douglas, Doyle, Pawlenty, and Sebelius:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on August 3, 2006, on behalf of the States of Kansas, Minnesota, Vermont, and Wisconsin. Your petition requests that FDA promptly issue guidance documents outlining the specific approval requirements for forms of insulin and human growth hormone that are therapeutically equivalent to products currently approved by the FDA.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0306

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