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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives Committee on Energy and Commerce Washington, DC 20515-6115

JOHN D. DINGELL, MICHIGAN CHAIRMAN

August 20, 2007

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The Honorable Andrew C. von Eschenbach, M.D. Commissioner
U. S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857-0001

Dear Dr. von Eschenbach:

Under Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the ability of the Food and Drug Administration (FDA) to protect the American public from excessive risks associated with imported drug products. As part of those investigations, we are examining FDA inspections of foreign drug manufacturing facilities.

I have instructed Committee staff to accompany FDA personnel on inspections of drug manufacturing plants in both China and India. To aid the Committee's oversight of these inspections, I request that you produce the inspection reports of the following drug manufacturing facilities, which Committee staff will be visiting with FDA beginning the week of August 27, 2007: Northeast General Pharmaceutical Factory and Shaanxi Hanjiang Pharmaceutical Group Co., Ltd. (China) and Glenmark Pharmaceuticals Ltd. (India).

Please provide the requested information as soon as possible so Committee staff may review the documents prior to their departure on August 26, 2007. If you have any questions regarding these requests, please have your staff contact Joanne Royce with the Committee staff at (202) 226-2424.

Sincerely,

JOHN D. DINGELL CHAIRMAN The Honorable Andrew C. von Eschenbach, M.D. Page 2

cc: The Honorable Joe Barton, Ranking Member Committee on Energy and Commerce

The Honorable Bart Stupak, Chairman Subcommittee on Oversight and Investigations

The Honorable Ed Whitfield, Ranking Member Subcommittee on Oversight and Investigations