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February 3, 2003

Via Facsimile

Dockets Management Branch
Food and Drug Administration
Dept. of Heath and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket 02P-0256

Dear Sir/Madam:

Response of Mylan Pharmaceuticals Inc.
to the Submission of Teva Pharmaceuticals USA, Inc.

Mylan Pharmaceuticals Inc. (hereinafter "Mylan") respectfully submits this brief response to the submission of Teva Pharmaceuticals USA, Inc. (hereinafter "Teva") with respect to the above docketed matter. Teva mischaracterizes the basis for Mylan's citizen petition (the "citizen petition"). The issue raised in the citizen petition is not Teva's "inadvertent 'failure to include a minor piece of information' in its ANDA." It is clear from the record, and Teva has not disputed, that there was no DMF filed for Teva to reference. The failure to file a DMF is not a "de minimus oversight." It is the failure to file a basic and essential part of the ANDA. Without a DMF, the agency cannot evaluate the processes, components and facilities used to produce an active drug substance. Teva's omission is not a typographical error nor is it an oversight. Teva's ANDA was incomplete because there was no filed DMF it could reference.

Moreover, it would not be a "policy shift" for FDA to refuse to file Teva's ANDA for failure to have a filed DMF to reference. On May 12, 1998 the FDA refused to file an ANDA submitted by Mylan because Mylan failed to provide authorization from the DMF holder with its

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application. See May 12, 1998 letter from FDA attached as Exhibit A. Mylan's Citizen Petition simply requests the agency to follow its regulations and past practices.

Respectfully submitted on behalf of
Mylan Pharmaceuticals Inc.,

Elizabeth A. Leff

EAL:whc

cc: Elizabeth Dickenson, Esq.