DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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John O'Donnell
Chief Scientific Officer
Mylan Laboratories Inc.
1500 Corporate Drive, Suite 400
Canonsburg, PA 15317-8574

Carolyn Myers, Ph.D.
President
Mylan Technologies Inc.
110 Lake Street
St. Albans, VT 05478-2266

Re: Docket No. 2006P-0123/CP1 & PSA1

Dear Dr. Myers and Mr. O'Donnell:

This letter concerns the docket for your citizen petition (petition) dated March 16, 2006, and petition for stay of action (PSA) dated July 24, 2007, regarding overlays for fentanyl patches, 2006P-0123/CP1 and PSA1.

On March 22, 2007, at the request of Mylan Technologies Inc. (Mylan), Food and Drug Administration (FDA) representatives met with Mylan Laboratories Inc., Mylan Technologies, Inc., and Mylan's invited guests Johnson & Johnson/Ortho-McNeil, Inc./Janssen L.P./Alza Corporation (J&J).[1] Alza Corporation is the holder of approved new drug application (NDA) 19-813 for Duragesic (Fentanyl Transdermal System).

After that meeting, in a correspondence dated May 15, 2007, you characterized the March 22 meeting on the petition as a "private meeting" under 21 CFR 10.65(c) and requested that FDA treat as confidential minutes generated from that meeting. Under applicable regulations relating to citizen petitions, FDA is unable to grant this request and, instead, intends to place FDA minutes of the March 22 meeting in the petition docket.

Initially when Mylan contacted the Office of Generic Drugs (OGD) regarding a potential meeting, Mylan indicated that it sought to discuss safety issues related to transient peaks in blood levels observed during some pharmacokinetic (PK) studies and the effects of patch manipulations on PK in some recent exploratory studies. However, when the briefing package for that meeting was submitted, Mylan indicated that it wanted "to discuss issues raised in our Citizen's Petition (Docket No. 2006P-0123)." At the beginning of the March 22 meeting, Gary Buehler, Director of OGD, announced that the issues Mylan and J&J wanted to discuss were issues that were raised in the petition and that, as a result, the FDA attendees would be in listening mode only and no decisions would be reached. Mylan itself also subsequently confirmed that it arranged the meeting to attempt to obtain resolution of the issues raised in the petition. As you state on p. 4 of your PSA, "In light of the lack of a decision by the Agency on

[1] Janssen L.P., Alza Corporation, and Ortho-McNeil, Inc., are all members of the Johnson & Johnson family of companies.

2006P-0123

LET 2

the Citizen Petition, Mylan requested the Agency to schedule a meeting with all stakeholders to discuss the resolution of the Petition. On March 22, 2007, the Agency held a meeting with the sponsors, but no resolution was provided by the Agency."

Although Mylan now characterizes the March 22 meeting as a meeting for "all stakeholders," as noted above, the March 22 meeting invitees and attendees did not include all of the stakeholders with an interest in the petition — its participants were limited to Mylan and J&J. Other applicants with pending or approved applications for fentanyl patches, physicians who prescribe fentanyl patches, and patients who purchase and use them, all of whom might potentially be affected by the issues raised in the petition, were not invited and not privy to the information presented there. Despite this limited attendance, the information presented at the March 22 meeting may be important for FDA's decision making process on the petition and may also be of interest to all stakeholders with an interest in your petition, not simply to Mylan and J&J.

Under FDA's regulations governing citizen petitions at 21 CFR 10.30(h)(1), in reviewing a petition, FDA may use "[c]onferences, meetings, discussions and correspondence." Under 21 CFR 10.30(i), the administrative record for resolution of the petition shall include, among other things, "the record, consisting of any transcripts, *minutes of meetings*, reports, Federal Register notices, *and other documents resulting from the operational procedures specified in [21 CFR 10.30(h)*], except a transcript of a closed portion of a public advisory committee meeting" (emphasis added). Moreover, in the case of a citizen petition, "the administrative record specified in [21 CFR 10.30(i)] is the *exclusive* record for the Commissioner's decision" (21 CFR 10.30(j) (emphasis added)).

Mylan was and is aware that the issues discussed in the March 22 meeting related to its pending petition and, by its own admission, convened that meeting to discuss resolution of those precise issues. Mylan was also on notice that under governing FDA regulations, minutes of meetings (other than closed advisory committee meetings) with respect to a pending citizen petition are public and will be considered part of the publicly available administrative record for the petition.

Mylan argues that in spite of the fact that the March 22 meeting was called to discuss resolution of issues in its petition, it was nonetheless a "private meeting"[2] under 21 CFR 10.65 for which the minutes should not be made publicly available. However, even under 21 CFR 10.65, "an official transcript, recording, or memorandum summarizing the substance of a meeting described in this section will be prepared by a representative of FDA" and "FDA promptly will file in the appropriate administrative file memoranda of meetings prepared by FDA representatives" (21 CFR 10.65(e) and (f)). Because, by Mylan's own admission, the March 22 meeting was called to resolve the issues in the petition and the petition's administrative record is the "exclusive" record for the decision on the petition, the "appropriate administrative file" for minutes of that meeting is the publicly available petition docket.

FDA further notes that in submitting its citizen petition as required by regulation, Mylan submitted a certification (on p. 6 of the original petition) that states, "[t]he undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information

[2] We note that Mylan's characterization of this meeting as a private meeting directly conflicts with its description in the PSA as a meeting involving "all stakeholders."

known to the petitioner, which are unfavorable to the petitioner" (21 CFR 10.30). Thus, Mylan was obligated to include in the docket for the petition information discussed at the March 22 meeting. Such information, by Mylan's own admission, bears on resolution of the petition and is information on which it sought to have FDA rely in resolving the issues in the petition.[3]

Therefore, in light of the fact that Mylan acknowledges that the March 22 meeting was called to discuss resolution of the issues in its citizen petition and that the information presented at that meeting bears on resolution of those issues, FDA intends to place the meeting minutes in Docket No. 2006P-0123.

In addition, a copy of this letter regarding your petition will be placed in Docket No. 2006P-0123 in the Division of Dockets Management, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

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

cc: ALZA Corporation
c/o Johnson & Johnson Pharmaceutical Research and Development, L.L.C.
Attention: Michael H. Kaufman
920 Route 202 South
P.O. Box 300
Raritan, New Jersey 08869-0602

Jeffrey M. Senger
Office of the Chief Counsel
Food and Drug Administration
Health and Human Services

[3] We note that as a company that has frequently complained about the citizen petition process and has expressed an interest in its reform, Mylan should have a particular desire to ensure that issues raised in a citizen petition are resolved in an open, transparent manner that allows all parties with an interest in the petition to obtain access to and comment on the information on which FDA's resolution of the petition may rely.