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July 23, 2012

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
Food and Drug Administration
Department of Health and Human Services
WO51/Room 6133
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Dr. Woodcock:

Public Citizen, representing more than 300,000 members and supporters nationwide, is writing to bring to your attention a concerning delay in the Food and Drug Administration's (FDA's) public disclosure of new drug application (NDA) approval packages, including those related to NDA supplements. Given the public's strong interest in this information, Public Citizen seeks a commitment from the FDA to affirmatively post these packages on its website within three months of approval.

In the past, the FDA expeditiously provided to the public NDA approval packages for new drugs, indications, and formulations by posting this information on the agency's website within a few months of approval. Public Citizen relies heavily on access to these approval packages, from which we base our scientific reviews for the benefit of the public. These approval packages provide information we need to understand the FDA's assessment of both the benefits and adverse effects of new drugs and new indications for drugs previously approved by the FDA.

In recent months, however, the affirmative public disclosure of NDA approval packages by the FDA has either decreased or, in some cases, been greatly delayed. As a result, we are prevented from analyzing the information contained in the approval packages for the benefit of consumers who rely on us to provide them with information needed for the wise use of new drugs or previously approved drugs for new indications.

To gain access to this information, Public Citizen has had to resort to Freedom of Information Act (FOIA) requests for five recent NDA approval packages listed in the enclosed appendix. In May, the FDA, at our request, provided estimated dates for the posting of three of these packages, which seems to have spurred the release of two, but the date for posting one of these is still months in the future. The time that elapses between our initial requests and posting presents a delay that is inconsistent with the agency's statutory obligations under FOIA. Moreover,

FOIA's time limit for a response has since passed for all of the requests concerning packages that have not yet been posted.

The public has a strong interest in consistent and expeditious public access to NDA approval packages in order to gain access to the more thorough analysis of the risks and benefits as presented by FDA scientists. In light of that interest, Public Citizen asks that FDA post all NDA approval packages on its website within three months of approval. Thank you for your consideration of this important issue. We look forward to hearing your response.

Sincerely,

Elizabeth Barbehenn, Ph.D.
Researcher
Public Citizen's Health Research Group

Michael A. Carome, M.D.
Deputy Director
Public Citizen's Health Research Group

Sidney M. Wolfe, M.D.
Director
Public Citizen's Health Research Group

Cc: Margaret Hamburg, Commissioner, FDA
Elizabeth Dickinson, Chief Counsel, FDA
Frederick J. Sadler, Office of Commissioner, Division of FOI, FDA

Appendix

Drugs for which Public Citizen has requested approval packages:

Drug	**NDA No.**	**Date of approval**	**Date of request (File number)**	**Estimated date of posting (as of May 2012) and/or date posted**	**Time between approval and posting (months)**
Juvisync	202343	**October 7, 2011**	December 20, 2011 (2011-9471)	Estimated: September 2012 **Posted: July 2012**	9
Intermezzo	22328	**November 23, 2011**	December 13, 2011 (2011-9291)	Estimated: December 2012	13 (estimated)
Bydureon	22200	**January 27, 2012**	January 30, 2012 (2012-667)	Estimated: June 2012 **Posted: June 2012**	5
Albuterol sulfate; Ipatropium bromide	21747	**October 7, 2011**	May 23, 2012 (F12-3770)		9 (as of July 2012)
Azilsartan Kamedoxomil; Chlorthalidone	202331	**December 20, 2011**	May 23, 2012 (F12-3770)		7 (as of July 2012)