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March 6, 2015

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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

Re: Celgene Corporation and Abraxis BioScience LLC Citizen Petition

To Whom it May Concern:

On behalf of Celgene Corporation and Abraxis BioScience LLC ("Celgene"), I hereby submit the attached Citizen Petition to request that the Food and Drug Administration ("FDA") establish appropriately stringent standards, as set forth in the Petition, with respect to: (1) approval of oncologic drug products incorporating nanotechnology, (2) the review and approval of any abbreviated new drug application ("ANDA") relying on the approval of ABRAXANE® (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) as a reference listed drug, and (3) any 505(b)(2) new drug application ("NDA") for any similar product referencing ABRAXANE or paclitaxel.

This Petition is being submitted under Section 505 of the Federal Food, Drug, and Cosmetic Act, and in accordance with the requirements set forth in 21 C.F.R. §§ 10.20 and 10.30. Should you have any questions regarding this Petition, please do not hesitate to contact me.

Respectfully submitted,

Daniel A. Kracov

Counsel to Celgene Corporation and
Abraxis BioScience LLC

Enclosures

FDA-2015-P-0732

CITIZEN PETITION

Requesting that the Food and Drug Administration establish stringent standards with respect to any abbreviated new drug application relying on the approval of ABRAXANE® (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) as a reference listed drug, and any 505(b)(2) new drug application for any similar product referencing ABRAXANE or paclitaxel

Celgene Corporation
and
Abraxis BioScience, LLC, a wholly owned subsidiary of Celgene Corporation

March 6, 2015

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