Advancing Transfusion and Cellular Therapies Worldwide

AABB Center for CELLULAR THERAPIES

August 8, 2016

Leslie Kux
Associate Commissioner for Policy
Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA–2013–N–0579 for ‘‘Agency Information Collection Activities; Proposed Collection; Comment Request; Biological Products: Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Deviations in Manufacturing; Forms FDA 3486 and 3486A’’

Dear Ms. Kux,

AABB appreciates the opportunity to comment on “Agency Information Collection Activities; Proposed Collection; Comment Request; Biological Products: Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Deviations in Manufacturing; Forms FDA 3486 and 3486A.” AABB is an international, not-for-profit association representing individuals and institutions involved in the fields of transfusion medicine and cellular therapies. The association is committed to improving health through the development and delivery of standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership includes physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers. AABB members are located in more than 80 countries and AABB accredits institutions in over 50 countries.

Forms FDA 3486 and 3486A are required for use by biological product manufacturers to report biological product deviations (BPD) that may affect the safety, purity or potency of a distributed product in accordance with 21 CFR §§ 600.14 or 606.171. Also, the forms are used by manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) to report HCT/P deviations in accordance with 21 CFR § 1271.350(b).

Some AABB members and member facilities engaged in the manufacture of biologic products manufacture multiple products (or lots) from a single starting cell source. In these cases, Forms FDA 3486 and 3486A are cumbersome when attempting to report a single biological product deviation that affects multiple products / lots as required under 21 CFR § 1271.350(b) since most facilities only report a few at once. AABB encourages FDA to permit all facilities, regardless of

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the number of products they report, to attach a document to the forms rather than requiring them to retype the information. This improvement will reduce the burden on facilities and improve the accuracy of the information reported to FDA by limiting the risk of human error involved in their submissions to FDA. If FDA does not accept this recommendation, AABB encourages FDA to reduce the burden on facilities by capping the forms at a much lower number of products / lots than the current maximum of 100.

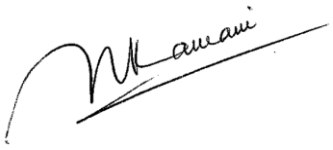
In addition, AABB believes Forms FDA 3486 and 3486A can be improved by incorporating technology to permit barcode scanning for relevant fields. Many facilities already have this technological capability, or will have this ability within the next few years. AABB believes that this improvement could reduce typographical human errors, which will result in more accurate submissions to FDA.

AABB recommends that FDA reduce the burdens associated with Forms FDA 3486 and 3486A by (1) permitting all facilities to attach additional documentation – e.g. spreadsheet – to report a biological product deviation, regardless of the number of products to be reported, and (2) incorporating technology to permit barcode scanning for relevant fields which could reduce typographical human errors.

AABB respectfully requests that FDA consider modifying Forms FDA 3486 and 3486A with these improvements, which would establish a more user-friendly interface, minimize the chance for errors, and accommodate a common manufacturing practice in the cell therapy product manufacturing sector.

Should you have any questions regarding these comments or would like additional information, please contact me at nkamani@aabb.org.

Sincerely,



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AABB