DIVISION OF DOCKETS MANAGEMENT (HFA–9)

FOR FURTHER INFORMATION CONTACT:

Leslie Kux, Associate Commissioner for Policy.

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For supplementary information:

I. Background

In the Federal Register of August 1, 2014 (79 FR 44803), FDA published the notice of availability for a draft guidance for industry #218 entitled “Cell-Based Products for Animal Use” giving interested persons until September 30, 2014, to comment on the draft guidance. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated August 1, 2014.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Cell-Based Products for Animal Use. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 and 21 CFR 511.1 have been approved under OMB control numbers 0910–0032 and 0910–0117, respectively.

IV. Comments

Interested persons may submit either electronic comments regarding this document to http://www.reginfo.gov/public/do/PRAMain. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm or http://www.regulations.gov.

Dated: June 8, 2015.

Leslie Kux,
Associate Commissioner for Policy.