4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0634]

Draft Guidance for Industry on Cell-Based Products for Animal Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry #218 entitled "Cell-Based Products for Animal Use." This draft guidance describes FDA's Center for Veterinary Medicine's (CVM) current thinking on cell-based products for animal use that meet the definition of a new animal drug. This draft guidance is for firms and individuals developing cell-based products, including animal stem cell-based products (ASCPs).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lynne Boxer, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0611, lynne.boxer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #218 entitled "Cell-Based Products for Animal Use." CVM is aware that many veterinary therapies may be produced using cell-based products. Developers of such products for veterinary use have approached CVM for clarification regarding the regulation of these products. This draft guidance for industry describes CVM's current thinking on cell-based products for animal use that meet the definition of a new animal drug.

Cell-based products meeting the definition of a new animal drug are subject to the same statutory and regulatory requirements as other new animal drugs. Although this draft guidance relates to other cell-based products, this draft guidance focuses on ASCPs meeting the definition of a new animal drug.

This draft guidance addresses the following topics:

- How existing regulations apply to cell-based products for veterinary use;
- a common vocabulary for ASCPs;
- a risk-based category structure for ASCPs; and
- industry interaction with CVM early in product development.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft 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.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

V. Electronic Access

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

Dated: July 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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