4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket Nos. FDA-2005-N-0033, FDA-2008-N-0115]

# Use of Materials Derived from Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants; Reporting Information Regarding Falsification of Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA, Agency, we) is announcing the withdrawal of two proposed rules that published in the *Federal Register*. These proposed rules are not currently considered viable candidates for final action. FDA is taking this action because the regulatory requirements set forth in the proposed rules are not needed at this time to protect the public health.

DATES: As of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], the proposed rules published on January 12, 2007, at 72 FR 1582, and February 19, 2010, at 75 FR 7412 are withdrawn.

ADDRESSES: For access to the docket, go to https://www.regulations.gov and insert the docket number found in brackets in the heading of this document into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian Pendleton, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4250, Silver Spring, MD 20993-0002, 301-796-4614, brian.pendleton@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In 1990, FDA began a process of periodically conducting comprehensive reviews of its regulation process, including reviewing the backlog of proposed rulemakings that had not been finalized. As FDA removed many proposed rules not finalized, the Agency implemented a process of reviewing existing proposed rules every 5 years.

As part of this process and the Administration's regulatory reform initiative, we continue to conduct reviews of existing proposed rules. The review determines if the proposals are outdated, unnecessary, or can be revised to reduce regulatory burden while allowing FDA to achieve our public health mission and fulfill statutory obligations.

As part of these efforts, FDA is withdrawing the following proposed rules:

| | Title of Proposed Rule | Publication Date, *Federal Register* Citation | Docket No. | Reason for Withdrawal |
|---|---|---|---|---|
| 1 | *Use of Materials Derived from Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants* | January 12, 2007, 72 FR 1582 | FDA-2005-N-0033 | We are withdrawing the proposed rule because the risk to public health posed by the potential use of materials derived from cattle in medical products has been significantly diminished since the issuance of the proposed rule, and we believe we can address any potential concerns through application of our premarketing review authority. |
| 2 | *Reporting Information Regarding Falsification of Data* | February 19, 2010, 75 FR 7412 | FDA-2008-N-0115 | The rule is not needed to protect research subjects or to help ensure the integrity of clinical trial data submitted to FDA in support of marketing applications and petitions for product approvals. Existing regulations require study sponsors to notify FDA when |

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| | | | | they end an investigator's participation in an investigation (21 CFR 312.56(b)), and institutional review boards must notify us when they suspend or terminate their approval of research (21 CFR 56.113). Based on our review of recent data, we conclude that we are receiving adequate notice of falsification of data, and we do not believe that adopting the proposed requirements would provide us with substantial additional information. |

The withdrawal of the proposed rules does not preclude the Agency from reinstituting rulemaking concerning the issues addressed in the proposed rules listed in the table. Should we decide to undertake such rulemakings in the future, we will re-propose the actions and provide new opportunities for comment. Furthermore, these proposed rules' withdrawal is only intended to address the specific actions identified in this document, and not any other pending proposals that the Agency has issued or is considering. If you need additional information about the subject matter of the withdrawn proposed rules, you may review the Agency's website (https://www.fda.gov) for any current information on the matter.

Dated: September 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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