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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Chapter 1

[Docket No. FDA-2008-N-0622]

#### Withdrawal of Two Proposed Rules

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of two proposed rules that published in the Federal Register more than 5 years ago. These proposed rules are no longer considered viable candidates for final action. FDA is taking this action because these proposed rules are out of date.

DATES: The proposed rules are withdrawn on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Lisa M. Helmanis, Regulations Policy and Management Staff, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3326, Silver Spring, MD 20993-0002, 301-796-9135, email: Lisa.Helmanis@fda.hhs.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In 1990, FDA began a process of periodically conducting comprehensive reviews of its regulation process, including reviewing the backlog of notices of proposed rulemakings that were never finalized. As FDA removed many proposed rules that had not been finalized, the

Agency was able to clean out the backlog and implement a process of reviewing these proposed rules every 5 years. In the Federal Register of December 12, 2008 (73 FR 75625), FDA withdrew four proposed rules that were more than 5 years old that it did not intend to finalize.

Recently, FDA has conducted a review of proposed rules that are more than 5 years old, and is announcing the withdrawal the following two proposed rules:

|   | Title of Proposed Rule  | Publication Date & Docket No. | Reason for Withdrawal  |
|---|---|-------------------------------|--|
| 1 | Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation | 1/18/2001<br>00N-0989         | FDA has reconsidered our position on this issue and deemed our concerns from 2001 outdated. We will continue to assess whether rulemaking in this area is necessary, and if so, we will proceed with a new proposed rule.  |
| 2 | Crabmeat; Amendment of Common or Usual Name Regulation  | 4/23/1998<br>94P-0043         | This proposed rule is obsolete because FDA has created a new process that allows for routine updates to the seafood names without going through notice and comment rulemaking. See FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce. |

The withdrawal of these proposals identified in this document does not preclude the Agency from reinstituting rulemaking concerning the issues addressed in the proposals listed in the chart. Should we decide to undertake such rulemakings in the future, we will re-propose the actions and provide new opportunities for comment. Furthermore, this notice 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. The Agency notes that withdrawal of a proposal does not necessarily mean that the preamble statement of the proposal no longer reflects the current position of FDA on the matter addressed. You may wish to review the Agency's Web site (<http://www.fda.gov>) for any current guidance on the matter.

Dated: November 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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