

Prevention and the Agency for Toxic Substances and Disease Registry.

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Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0254]

Salmonella Contamination of Dry Dog Food; Withdrawal of Compliance Policy Guide

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; Withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of the compliance policy guide (CPG) entitled “Sec. 690.700 *Salmonella* Contamination of Dry Dog Food.” This CPG is obsolete.

DATES: The withdrawal is effective July 16, 2013.

FOR FURTHER INFORMATION CONTACT: Diane D. Jeang, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301-796-3890.

SUPPLEMENTARY INFORMATION: FDA issued the CPG entitled “Sec. 690.700 *Salmonella* Contamination of Dry Dog Food (CPG 690.700)” on October 1, 1980. CPG 690.700 was issued as a result of a human case of salmonellosis traced to dry dog food; a subsequent FDA-conducted survey of dry dog food; a risk analysis; and the development of an appropriate sampling technique to test dry dog food for *salmonella* organisms.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a new CPG to address all food for animals that may contain *salmonella* organisms, including dry dog food. This new CPG, entitled “Compliance Policy Guide Sec. 690.800 *Salmonella* in Food for Animals,” supersedes CPG 690.700 and makes CPG 690.700 obsolete. The notice of availability for CPG “Sec. 690.800 *Salmonella* in Food for Animals” is published elsewhere in this issue of the **Federal Register**.

FDA is withdrawing CPG 690.700, in its entirety, to eliminate obsolete compliance policy.

Dated: July 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-16973 Filed 7-15-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0378]

Compliance Policy Guide Sec. 690.800 *Salmonella* in Food for Animals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of guidance for our staff entitled “Compliance Policy Guide Sec. 690.800 *Salmonella* in Food for Animals” (the CPG). The CPG provides guidance to FDA staff on *Salmonella*-contaminated food for animals.

DATES: Submit either electronic or written comments on the CPG at any time.

ADDRESSES: Submit written requests for single copies of the CPG to the Food and Feed Policy Staff, Office of Policy and Risk Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the CPG.

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

FOR FURTHER INFORMATION CONTACT: Kim Young, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9207, kim.young@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance document entitled “Compliance Policy Guide Sec. 690.800 *Salmonella* in Food for Animals” (the CPG). The CPG provides guidance to FDA staff on *Salmonella*-contaminated food for animals. The CPG is being issued consistent with our good

guidance practices regulation (21 CFR 10.115). The CPG represents FDA’s current thinking on *Salmonella*-contaminated food for animals. 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.

In the **Federal Register** of August 2, 2010 (75 FR 45130), we announced the availability of a draft CPG entitled “Compliance Policy Guide Sec. 690.800 *Salmonella* in Animal Feed,” and gave interested persons an opportunity to submit comments by November 1, 2010, for us to consider before beginning our work on the final version of the CPG. In the **Federal Register** of October 29, 2010 (75 FR 66769), we published a notice extending the comment period until December 31, 2010. We received numerous comments on the draft CPG and have modified the final CPG where appropriate. The CPG announced in this notice finalizes the draft CPG announced on August 2, 2010.

Changes to the CPG include:

- The title of the CPG is changed from “*Salmonella* in Animal Feed” to “*Salmonella* in Food for Animals.” FDA made this change to clarify that the CPG covers all animal food. The term “food for animals” here includes pet food and animal feed.
- The term “Direct Human Contact Animal Feed” has been removed from the CPG, because commenters found the term to be confusing. The term pet food is now used instead. It is defined to mean food for pets and includes treats and chews for pets.

The CPG explains criteria that FDA personnel should consider in recommending enforcement action against food for animals that is adulterated due to the presence of *Salmonella*. In particular, the CPG provides regulatory action guidance relating to pet food or pet food ingredients that are contaminated with *Salmonella*. In addition, the CPG provides regulatory action guidance relating to animal feed and animal feed ingredients that are contaminated with certain *Salmonella* serotypes that are pathogenic to the particular species of animal for which the animal feed or animal feed ingredients are intended. The CPG also contains information that may be useful to regulated industry and the public.

This notice is related to two notices published elsewhere in this issue of the **Federal Register**, in which FDA is announcing: (1) The removal of 21 CFR 500.35 “Animal feeds contaminated with *Salmonella* microorganisms,” and

(2) the withdrawal of "Compliance Policy Guide Sec. 690.700 *Salmonella* Contamination of Dry Dog Food." The enforcement policy in the CPG supersedes the policies articulated in 21 CFR 500.35 and CPG Sec. 690.700.

II. Comments

Interested persons may submit either electronic comments regarding the CPG 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>.

III. Electronic Access

Persons with access to the Internet may obtain the CPG at either http://www.fda.gov/ora/compliance_ref/cpg/default.htm or at <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the CPG.

Dated: July 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-16975 Filed 7-15-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National

Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of patent applications.

Islet Beta Cell Only M3 Muscarinic Acetylcholine Receptor Knockout Mouse

Description of Technology: Researchers at NIH have developed islet beta cell M3 muscarinic acetylcholine receptor knockout mouse. The mice were generated by crossing floxed mouse M3 muscarinic acetylcholine receptor mice with mice in which Cre recombinase was controlled by the beta-cell specific rat insulin promoter (RIP-Cre mice).

Potential Commercial Applications: Study of the physiological role of beta-cell M3 muscarinic receptors in the regulation of glucose homeostasis and insulin release in vivo.

Competitive Advantages: Allows for study of the role of the M3 receptors in the pancreas without whole body effects confounding the results.

Development Stage: In vivo data available (animal)

Inventor: Jürgen Wess, Ph.D. (NIDDK)

Publication: Gautam D, et al. A critical role for beta cell M3 muscarinic acetylcholine receptors in regulating insulin release and blood glucose homeostasis in vivo. *Cell Metab.* 2006 Jun;3(6):449-61. [PMID 16753580]

Intellectual Property: HHS Reference No. E-452-2013/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Jaime M. Greene, M.S.; 301-435-5559; greenajaime@mail.nih.gov.

Transgenic Mice With Constitutively Active M3 Muscarinic Receptor in Islet Beta Cells

Description of Technology: Q490L point mutation was introduced into the rat M3 muscarinic receptor cDNA to confer persistent, constitutive (ligand-independent) activity. Expression of the M3 receptor mutant was placed under the control of a 650 bp fragment of the rat insulin promoter II (RIP II) to limit expression to the islet beta cell.

Potential Commercial Applications: Diabetes research, especially type II Diabetes.

Competitive Advantages: Beneficial metabolic effects of this mouse model include high basal insulin secretion, improved glucose tolerance, increased serum insulin, and resistance to high-fat diet-induced glucose intolerance and hyperglycemia.

Development Stage: In vivo data available (animal)

Inventor: Jürgen Wess, Ph.D. (NIDDK)

Publication: Gautam D, et al. Beneficial metabolic effects caused by persistent activation of beta-cell M3 muscarinic acetylcholine receptors in transgenic mice. *Endocrinology.* 2010 Nov;151(11):5185-94. [PMID 20843999]

Intellectual Property: HHS Reference No. E-453-2013/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Jaime M. Greene, M.S.; 301-435-5559; greenajaime@mail.nih.gov.

Transgenic Mice Overexpressing Islet Beta Cell M3 Muscarinic Acetylcholine Receptors

Description of Technology: Researchers at NIH have generated transgenic mice in which the M3 muscarinic receptor is overexpressed in pancreatic beta cells. This was done by placing the receptor gene under the control of the 650 bp rat insulin promoter II (RIP II). The resulting mice show a pronounced increase in glucose tolerance and enhanced plasma insulin levels. Strikingly, these mutant mice were resistant to diet-induced glucose intolerance and hyperglycemia.

Potential Commercial Applications: Diabetes research, especially type II Diabetes.

Competitive Advantages: These transgenic mice overexpress the M3 muscarinic acetylcholine receptor only in pancreatic beta cells but notably are resistant to diet-induced glucose intolerance and hyperglycemia.

Development Stage: In vivo data available (animal).

Inventor: Jürgen Wess, Ph.D. (NIDDK).

Publication: Gautam D, et al. A critical role for beta cell M3 muscarinic acetylcholine receptors in regulating insulin release and blood glucose homeostasis in vivo. *Cell Metab.* 2006 Jun;3(6):449-61. [PMID 16753580].

Intellectual Property: HHS Reference No. E-455-2013/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Jaime M. Greene, M.S.; 301-435-5559; greenajaime@mail.nih.gov.

An Improved System for Production of Recombinant Baculovirus

Description of Technology: Baculoviruses have been used for decades to produce proteins in insect cell hosts. Current systems for generating recombinant baculovirus have several shortcomings which prevent their easy use in high-throughput applications. The present