

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 1990D-0428]

### Human-Labeled Drugs Distributed and Used in Animal Medicine; Withdrawal of Compliance Policy Guide

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; withdrawal.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal of a compliance policy guide (CPG) that was issued on March 19, 1991.

**DATES:** *[Insert date of publication in the Federal Register]*.

**FOR FURTHER INFORMATION CONTACT:** Diane D. Jeang, Division of Compliance Policy (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-632-6833.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of July 30, 1992 (57 FR 33729), FDA announced the availability of a revised CPG 7125.35 entitled "Human-Labeled Drugs Distributed and Used in Animal Medicine." The CPG is being withdrawn because it is obsolete. This CPG explained how FDA would exercise its enforcement discretion with respect to the distribution and use of human-labeled drug products for use in animals.

The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) was signed into law on October 22, 1994. AMDUCA allows veterinarians to prescribe extralabel uses of approved animal drugs and approved human drugs for animals under certain conditions. An extralabel use must be by or on the

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order of a licensed veterinarian within the context of a veterinarian-client-patient relationship and must be in conformance with the implementing regulations published in part 530 (21 CFR part 530). A list of drugs specifically prohibited from extralabel use in animals is in § 530.41.

With the enactment of AMDUCA and the issuance of implementing regulations, FDA is withdrawing CPG 7125.35 because it is obsolete. On September 24, 1998, a CPG section 615.100 entitled “Extralabel Use of New Animal Drugs in Food-Producing Animals (CPG 7125.06)” was withdrawn for the same reason (63 FR 51074).

Dated: June 20, 2006.

**Margaret O’K. Glavin,**

*Associate Commissioner for Regulatory Affairs.*

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