DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 96N–0094]

Uniform Compliance Date for Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing January 1, 2000, as the uniform compliance date for food labeling regulations that are issued between January 1, 1997, and December 31, 1998. FDA has periodically announced uniform compliance dates for new food labeling requirements to minimize the economic impact of label changes. In 1992, FDA suspended this practice pending the issuance of regulations implementing the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). FDA recently reinstated this practice of with the establishment of a uniform compliance date of January 1, 1998.

DATES: Effective December 27, 1996; written comments by March 13, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFS–150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561.

SUPPLEMENTARY INFORMATION: FDA periodically issues regulations requiring changes in the labeling of food. If the effective dates of these labeling changes were not coordinated, the cumulative economic impact on the food industry of having to respond separately to each change would be substantial. Therefore, the agency periodically has announced uniform compliance dates for new food labeling requirements (see e.g., the Federal Registers of October 19, 1984 (49 FR 41019) and December 24, 1996 (61 FR 67710). Use of a uniform compliance date provides for an orderly and economical industry adjustment to new labeling requirements by allowing sufficient lead time to plan for the use of existing label inventories and the development of new labeling materials. This policy serves consumers' interests as well because the cost of multiple short-term label revisions that would otherwise occur would likely be passed on to consumers in the form of higher prices.

During the 1980's and into the early 1990's, FDA periodically issued final rules announcing new uniform compliance dates for food labeling regulations. The agency suspended the issuance of uniform compliance date final rules in 1992 because of the pending issuance of a number of new final regulations implementing the 1990 amendments. Most of these regulations are now in place and effective.

In the Federal Register of April 15, 1996 (61 FR 16422), FDA issued a proposal entitled ''Uniform Compliance Date for Food Labeling Regulations.'' In that document, FDA, among other things, proposed to reinstate its practice of periodically issuing uniform compliance dates as final rules. The comments to the proposal fully supported the agency's doing so. With the publication of this final rule, FDA is reinstating this practice.

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

FDA has examined the economic implications of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach that maximizes net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze options that would minimize the economic impact of that rule on small entities.

The establishment of a uniform compliance date does not impose either costs or benefits. For future labeling requirements, FDA will assess the costs and benefits of the uniform compliance date as well as the options of setting alternative dates, especially with regard to the impact on small entities. Therefore, the agency finds that the final rule is not a significant rule as defined by Executive Order 12866. Similarly, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. It has also determined that the rule is not a major rule for the purpose of congressional review (Pub. L. 104–121).

This action is not intended to change existing requirements for compliance dates contained in final rules published before publication of this final rule. Therefore, all final FDA regulations published in the Federal Register before December 27, 1996 will still go into effect on the date stated in the respective final rule.

The agency generally encourages industry to comply with new labeling regulations as quickly as feasible, however. Thus, when industry members voluntarily change their labels, it is appropriate that they incorporate any new requirements that have been published as final regulations up to that time.

Because FDA has already provided notice and an opportunity for comment on the practice of establishing uniform compliance dates by issuance of a final rule announcing the date, it finds any further rulemaking unnecessary. Nonetheless, under 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on whether this uniform compliance date should be modified or revoked.

Interested persons may, on or before March 13, 1997 submit to the Dockets Management Branch (address above) written comments regarding this final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday though Friday. After its review of any comments received to this final rule, FDA will either publish a notice providing its conclusions concerning the comments or will initiate notice and comment rulemaking to modify or revoke the uniform compliance date established by this final rule.

The new uniform compliance date will apply only to final FDA food labeling regulations that require changes in the labeling of food products and that publish after January 1, 1997, and before January 1, 1999. Those regulations will specifically identify January 1, 2000, as their compliance date. All food products subject to the January 1, 2000, compliance date must comply with the

appropriate regulations when initially introduced into interstate commerce on or after January 1, 2000. If any food labeling regulation involves special circumstances that justify a compliance date other than January 1, 2000, the agency will determine for that regulation an appropriate compliance date, which will be specified when the final regulation is published.

Dated: December 20, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32884 Filed 12–26–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 510 and 522

Animal Drugs, Feeds, and Related Products; Fomepizole

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Orphan Medical, Inc. The NADA provides for intravenous use of fomepizole solution as an antidote for ethylene glycol poisoning in dogs.

EFFECTIVE DATE: December 27, 1996.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Orphan Medical, Inc., 13911 Ridgedale Dr., suite 475, Minnetonka, MN 55305, is sponsor of NADA 141–075, which provides for the use of Antizol-Vet™ (sterile injectable fomepizole solution) for use as an antidote for ethylene glycol (antifreeze) poisoning in dogs who have ingested or are suspected of having ingested ethylene glycol. The drug is for veterinary prescription use only. The NADA is approved as of November 25, 1996, and the regulations are amended in part 522 (21 CFR part 522) by adding a new § 522.1004 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Orphan Medical, Inc., has not previously been added to the list of sponsors of approved applications in § 510.600(c) (21 CFR 510.600(c)). At this time, § 510.600(c)(1) and (c)(2) are amended to include entries for the firm.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning November 25, 1996, because no active ingredient (including any ester or salt of the active ingredient) has been previously approved in any other application filed under section 512(b)(1) of the act.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for ''Orphan Medical, Inc.,'' and in the table in paragraph (c)(2) by numerically adding a new entry for ''062161'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* * * *
Orphan Medical, Inc., 13911 Ridgedale Dr., suite 475, Minnetonka, MN 55305	062161
* * *	* * * *