

and other materials relating to the contemplated license should be directed to Thomas E. O'Toole, Deputy Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE, Mailstop E-67, Atlanta, GA 30333, telephone: (404) 639-6270; facsimile: (404) 639-6266. Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by CDC within sixty days of this notice will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552. A signed Confidential Disclosure Agreement will be required to receive a copy of any pending patent application.

Dated: May 10, 1999.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99-12206 Filed 5-13-99; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D-0389]

Final Guidance on FDA Approval of New Animal Drugs for Minor Uses and for Minor Species; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance document entitled "Guidance for Industry: FDA Approval of New Animal Drugs for Minor Uses and for Minor Species." This guidance document is intended to provide specific guidance on the means for generating effectiveness and safety data to support the approval of new animal drugs for minor uses and minor species.

DATES: Written comments may be provided at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Guidance for Industry: FDA Approval of New Animal Drugs for Minor Uses and for Minor Species" to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500

Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. Copies of this guidance document may also be obtained from the CVM home page at "http://www.fda.gov/cvm". Submit written comments on the guidance document to the Policy and Regulations Team (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT:

Margaret R. Oeller, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7581, e-mail: moeller@bangate.fda.gov.

SUPPLEMENTARY INFORMATION: The major purpose of this guidance document is to suggest means of generating effectiveness and safety data to support the approval of minor use new animal drugs. Minor use of a new animal drug is defined as use in a minor species or use in any animal species for a condition that is rare or that occurs in limited geographic areas. Minor species are defined by exclusion, as any species other than major species. Major species are defined as cattle, swine, chickens, turkeys, horses, dogs, and cats. According to current regulations, sheep are a minor species except with respect to human food safety data collection requirements, for which sheep are considered major species.

The guidance document, as applied to minor use new animal drugs, does not lessen the legal requirements for demonstrating the safety and effectiveness of a new animal drug. Instead, the guidance document suggests possible means of generating safety and effectiveness data to satisfy these requirements.

In the **Federal Register** of September 29, 1997 (62 FR 50952), FDA published a notice of availability of a draft guidance on this subject. The notice gave interested persons an opportunity to submit comments by December 29, 1997. Seven comments were received by industry and trade associations. FDA considered these comments and revised the draft guidance document where appropriate.

This guidance document is intended to reflect the current way that animal drugs are approved for minor species and minor uses. The Animal Drug Availability Act of 1996 required CVM to examine the way that these products are approved and to propose means to facilitate such approvals. In the **Federal Register** of October 29, 1998 (63 FR 58056), CVM published a notice of the availability of its report proposing several options to encourage animal

drug approvals for minor species and for minor uses. It is very likely that additional policies and programs will be implemented over the next few years to accomplish this goal. Because policies and programs may change, sponsors are encouraged to contact CVM early in project development to determine the most efficient path to approval of their products. If any program and policy changes affect the policies in this guidance, CVM will revise this final guidance.

The final guidance represents the agency's current thinking on the means of generating efficacy and safety data to support approval of new animal drug applications for minor use new animal drugs. 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 statute, regulations, or both. As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this guidance. CVM will periodically review the comments concerning the document and, when appropriate, amend the guidance.

Dated: May 5, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99-12179 Filed 5-13-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-1089]

Year 2000 (Y2K) Computer Compliance Guide; Guidance for FDA Personnel

AGENCY: Food and Drug Administration

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new compliance policy guide (CPG) entitled "Year 2000 (Y2K) Computer Compliance" (section 160-800). This guidance document represents the agency's current thinking on the manufacturing and distribution of domestic and imported products regulated by FDA using computer systems that may not perform properly before, or during, the transition to the year 2000 (Y2K). The text of the CPG is included in this notice. This compliance guidance document is an update to the Compliance Policy Guides Manual (August 1996 edition). It is a new CPG,

and it will be included in the next printing of the Compliance Policy Guides Manual. This CPG is intended for FDA personnel, and it is available electronically to the public.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of CPG section 160–800 entitled “Year 2000 (Y2K) Computer Compliance” to the Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852. Send two self-addressed adhesive labels to assist that office in processing your requests. Written comments should be identified with the docket number found in brackets in the heading of this notice and should be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A copy of the CPG is available on the FDA World Wide Web (WWW) site at “<http://www.fda.gov/ora/compliance-ref/cpg/cpggenl/default.htm>”. Scroll down the WWW CPG page to locate section 160–800.

FOR FURTHER INFORMATION CONTACT: Tom M. Chin, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–827–0410

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) is announcing the availability of a new CPG (section 160–800) entitled “Year 2000 (Y2K) Computer Compliance.” This CPG represents the agency’s current thinking on the manufacturing and distribution of domestic and imported products regulated by FDA using computer systems that may not perform properly before or during the transition to the year 2000. The text of the CPG is included in this notice.

This CPG is an update to the Compliance Policy Guides Manual (August 1996 edition). It is a new CPG, and it will be included in the next printing of the Compliance Policy Guides Manual.

This CPG is intended for FDA personnel, and it is available electronically to the public (address above). The CPG does not create or confer any rights for or on any person, and it does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulation, or both. The text of the CPG follows:

Sub Chapter 160—Regulatory

Sec. 160–800 Year 2000 (Y2K) Computer Compliance

(CPG 7153.15)

Introduction:

This compliance guidance document is an update to the Compliance Policy Guides Manual (August 1996 edition). It is a new Compliance Policy Guide (CPG) and will be included in the next printing of the Compliance Policy Guides Manual. The CPG is intended for Food and Drug Administration (FDA) personnel and is available electronically to the public. The CPG 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 statute, regulation, or both.

Background:

This guidance document represents the agency’s current thinking on manufacturing and distribution of domestic and imported products regulated by FDA using computer systems that may not perform properly prior to, or during the transition to the year 2000 (Y2K).

As the millenium approaches, there is concern regarding the impact of Y2K issues on the identity, strength, quality, purity, and potency as well as safety, efficacy, and availability of products regulated by FDA. It is the responsibility of industry to come into Y2K compliance as soon as possible.

The agency has taken steps to ensure that its own computer systems will be ready for the transition to the year 2000. The agency’s mission critical computer systems have been checked and Y2K problems have been corrected. Those systems are currently undergoing independent verification and validation by a third party to ensure that they are Y2K compliant.

The statutory provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Public Health Service Act (PHSA) require the regulated industries to ensure that their products are in compliance with the requirements of the FFDCA, PHSA, and regulations. Further, the statutory provisions and the regulations also contain requirements concerning the equipment, machinery, and systems used in product manufacture and distribution.

Most products regulated by FDA are vulnerable to Y2K computer problems. A manufacturer’s failure to properly address a Y2K problem in their automated manufacturing, packaging, labeling or distribution processes could result in products that are adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act. In addition, FDA regulated computer automated products such as automated medical devices and FDA regulated computer software products such as blood establishment software could become adulterated or misbranded, if they contain a Y2K error and the manufacturer fails to take adequate corrective or preventive action.

FDA believes that companies should be taking actions to ensure that their equipment,

machinery, and systems used in product manufacture, control, storage and distribution are Y2K compliant. Those actions should include appropriate steps necessary to prevent Y2K problems that could affect the identity, strength, quality, purity, and potency as well as safety, effectiveness or reliability in general of any regulated product on the market.

To provide industries with information and guidance on Y2K issues, FDA has been alerting them in direct correspondence, speeches, public appearances, meetings, workshops, and guidance documents. The letters to the industry, guidance documents, other background information and links to Y2K information resources are available at the FDA Internet site. (<http://www.fda.gov>)

Policy:

This compliance policy guide (CPG) applies to all domestic and imported products regulated by FDA:

I. Industry Responsibility

Firms should pursue timely assessment, conversion, testing and validation of systems to allow sufficient time to identify and correct problems before they have any adverse impact on product quality or product availability. To minimize risks, firms should verify and validate systems that may affect product identity, strength, quality, purity or potency as well as safety, effectiveness or reliability in general. Also, FDA has urged industry to develop contingency plans that address all aspects of the manufacturing, supply and distribution systems to ensure that acceptable production levels are maintained to meet critical public health needs.

It is incumbent upon regulated industry to provide accurate and timely Y2K readiness information to address public concerns. FDA will continue to work with regulated industries to disseminate and exchange information relating to Y2K issues in order to avert Y2K problems before they become public health or regulatory issues.

II. Form FDA 483 Inspectional Observations

An FDA inspectional observation that a firm is not Y2K compliant should not be listed on form FDA 483. However, observations regarding specific process or product deficiencies related to the Y2K problem should be listed on the Form FDA 483.

III. Product Correction or Removal Actions

When an FDA regulated product held for sale or in commercial distribution is relabeled, returned, reprocessed, repaired, or replaced to resolve a problem caused by a Y2K computer error before the problem is manifested, the action will be considered a market withdrawal. (21 CFR 7.3(j))

However, if the correction or removal action is not completed before the adverse effect of the Y2K problem is manifested in a distributed product, the correction or removal action will be considered a recall. (21 CFR Part 7) For example, an action to recover a drug product because of an error in expiration dating can be classified as a recall, if the error is manifested in the actual date printed on the label of a drug in commercial

distribution. On the other hand, an action to replace software to correct a yet-to-be-manifested Y2K error in blood donor deferrals or in radiation dose calculations could be a market withdrawal, if that action is completed for all affected products in commercial distribution prior to the first date impacted by the Y2K failure.

For medical devices, if on or after May 18, 1998, (62 FR 27191 May 19, 1997) a manufacturer or importer initiates a correction or removal of medical devices to address a Y2K problem and that action is undertaken to reduce a risk to health, then the firm must report their action to FDA in accordance with the Corrections and Removals Regulation (21 CFR Part 806), regardless of whether or not there has been a malfunction related Y2K.

IV. Enforcement Discretion

The agency may exercise enforcement discretion and take into consideration any unusual or extenuating circumstance(s) that may have a bearing on a decision regarding enforcement action.

Regulatory Action Guidance:

I. Where regulated establishments and products are not compliant with laws and regulations administered by FDA because of Y2K computer issues, decisions on whether or not to pursue regulatory action should be based on an agency assessment of several factors including the following:

A. Products

1. Evaluate whether there is an existing or a potential risk to the public health (for example, specific patient populations or disease conditions) and the impact on product quality, intended purpose, function and/or use of the product. If it is a critical use or critical need product, assess its continued availability and whether there is/are the same or suitable substitute product(s) available to meet the anticipated need; and
2. Evaluate the firm's efforts to develop and initiate a Y2K contingency plan, implement suitable and timely risk assessment, prevention, and correction efforts, including efforts to inform potential users, re-label, return, reprocess, repair, or replace the product identified as Y2K non-compliant.

B. Establishments

In addition to the two items above (A1 and A2), where regulated establishments market violative products resulting from Y2K computer problems, determine responsibility to identify and correct Y2K problems prior to marketing the violative products.

II. District offices should consult with the respective center program monitor(s) (where appropriate) and/or center compliance officer(s) prior to recommending regulatory actions. District offices should obtain concurrence of the respective center program monitor(s) (where appropriate) and/or center compliance office(s) before issuing a warning letter regarding a Y2K computer problem.

Regulatory action with respect to product or process deficiencies caused by a Y2K computer problem must be based on applicable regulations and statutes. Therefore, regulatory citations should reference such regulations.

Dated: May 4, 1999.

Gary Dykstra,

Deputy Associate Commissioner for Regulatory Affairs.

[FR Doc. 99-12178 Filed 5-13-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-1072-N]

Medicare Program; June 14, 1999, Meeting of the Practicing Physicians Advisory Council

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council. This meeting is open to the public.

DATES: The meeting is scheduled for June 14, 1999, from 8:30 a.m. until 5 p.m., e.s.t.

ADDRESSES: The meeting will be held in the Multipurpose Room/Auditorium, 1st Floor, Health Care Financing Administration Building, 7500 Security Boulevard, Baltimore, Maryland 21244.

FOR FURTHER INFORMATION CONTACT: Aron Primack, M.D., M.A., F.A.C.P., Executive Director, Practicing Physicians Advisory Council, Room 435-H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201, (202) 690-7874. News media representatives should contact the HCFA Press Office, (202) 690-6145.

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Health and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Health Care Financing Administration not later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare or Medicaid in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members must be doctors of medicine or osteopathy authorized to practice medicine and surgery by the States in which they practice. Members have been invited to serve for overlapping 4-year terms. In accordance with section 14 of the Federal Advisory Committee Act, terms of more than 2 years are contingent upon the renewal of the Council by appropriate action before the end of the 2-year term.

The Council held its first meeting on May 11, 1992.

The current members are—Jerold M. Aronson, M.D.; Richard Bronfman, D.P.M.; Wayne R. Carlsen, D.O.; Mary T. Herald, M.D.; Sandral Hullett, M.D.; Stephen A. Imbeau, M.D.; Jerilynn S. Kaibel, D.C.; Marie G. Kuffner, M.D.; Derrick K. Latos, M.D.; Dale Lervick, O.D.; Sandra B. Reed, M.D.; Susan Schooley, M.D.; Maisie Tam, M.D.; Victor Vela, M.D.; and Kenneth M. Viste, Jr., M.D. The Council chairperson is Marie G. Kuffner, M.D.

Council members will be updated on the following subjects—The acquisition of Provider Identification Numbers; Quality Improvement Activities as they relate to the Peer Review Organization Sixth Scope of Work; Managed Care Provider Protections under Medicare+Choice; Negotiated Rulemaking for Laboratories, and items and recommendations made at previous meetings.

The agenda will provide for discussion and comment on the following topics:

- Doctors' Readiness for Y2K. (How can HCFA reach and encourage practicing physicians to test their systems and equipment to be sure of their Y2K readiness?)
- HCFA's New Coverage Process.
- Requirements for Lead Screening.

Individual physicians or medical organizations that represent physicians that wish to make 5-minute oral presentations on the agenda issues should contact the Executive Director by 12 noon, May 21, 1999, to be scheduled. The number of oral presentations may be limited by the time available. A written copy of the presenter's oral remarks should be submitted to the Executive Director no later than 12 noon, May 28, 1999, for distribution to Council members for review prior to the meeting. Physicians and organizations not scheduled to speak may also submit