DEPARTMENT OF HEALTH AND HUMAN SERVICES

Program Support Center; Senior Executive Service; Performance Review Board Members

Title 5, U.S. Code, Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that appointment of Performance Review Board members be published in the Federal Register.

Dated: September 30, 1996.

Lynnda M. Regan,

Director, Program Support Center.

The following persons will serve on the Performance Review Board which oversees the evaluation of performance appraisals of Senior Executive Service members of the Department of Health and Human Services in the Program Support Center:

John C. West, Chairperson
Lawrence S. Cohan
Luana Reyes
William A. Robinson, M.D.

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BILLING CODE 4160–17–M

Food and Drug Administration

[Docket No. 95D–0377]

Advertising and Promotion; Guidances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The agency is publishing two guidances entitled ''Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data'' and ''Guidance for Industry Funded Dissemination of Reference Texts.'' These guidances relate to the dissemination, by sponsors of human and animal drugs, medical devices, and biological products of certain reprints of journal articles and reference texts (medical textbooks and compendia), which contain information concerning FDA-approved products that may not be consistent with the approved labeling for the products. These guidances describe the circumstances under which the agency intends to allow the dissemination of these reprints and reference texts to health care professionals. These guidances are intended to assist the agency in fulfilling its mission to help ensure the safety and effectiveness of human and animal drugs, medical devices, and biological products. The full texts of these guidances are published in this document.

FOR FURTHER INFORMATION CONTACT:
Regarding general questions: Ilisa B. G. Bernstein, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, rm. 15–74, Rockville, MD 20857, 301–827–3380, or via Internet at IBERNSTE@BANGATE.FDA.GOV;
Regarding human drugs: Patrick O'Brien, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, rm. 17B–17, Rockville, MD 20857, 301–827–3901, or via Internet at OBRIENP@CDER.FDA.GOV;
Regarding animal drugs: Edward L. Spenser, Division of Surveillance (HFV–210), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1722, or via Internet at ESPENSER@BANGATE.FDA.GOV;
Regarding medical devices: Byron L. Tart, Center for Devices and Radiological Health (HFZ–302), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20879, 301–594–4639, or via Internet at BXT@FDADR.CDER.FDA.GOV;
Regarding biological products: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–202), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, or via Internet at STIFANO@CBER.FDA.GOV

SUPPLEMENTARY INFORMATION: In the Federal Register of December 8, 1995 (60 FR 63384), FDA published and sought public comment on two draft guidances entitled ''Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data'' and ''Guidance for Industry Funded Dissemination of Reference Texts.'' These guidances relate to the dissemination, by sponsors of human and animal drugs, medical devices, and biological products, of certain reprints of journal articles and reference texts (medical textbooks and compendia), which contain information concerning FDA-approved products that may not be consistent with the approved labeling for the products.

The agency received over 57 comments in response to the request for comments on the draft guidances. The comments came from drug and device manufacturers, professional health organizations, industry trade organizations, patient advocacy organizations, health communications specialists, attorneys, and health professionals. The agency has reviewed and considered these comments in its analysis of whether and what changes should be made in finalizing these guidances. As a result of this analysis, the agency has determined that no changes need to be made to the ''Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data.'' The ''Guidance for Industry Funded Dissemination of Reference Texts'' remains essentially unchanged; except in the discussion of circumstances for dissemination of reference texts, FDA added an additional circumstance concerning product promotion, as noted below.

The agency received several comments claiming that the guidance on dissemination of certain reprints does not go far enough, arguing that companies should be permitted to disseminate any article they choose, regardless of what information is discussed in the article or whether the information is consistent with the approved product labeling. The agency also received several comments that gave specific suggestions of the types of articles that should be permitted under a policy with a broader scope (e.g., all peer-reviewed articles, technical reports). FDA believes that the guidances that are the subject of this notice strike the proper balance between the need for an exchange of reliable scientific data and information within the health care community, and the statutory requirements that prohibit companies from promoting products for unapproved uses. However, the agency will continue to evaluate its policies related to the advertising and promotion of FDA-regulated products, and these guidances are just one part of its policy in this area.

The agency also received comments seeking clarification of certain aspects of the guidances. Although these comments were considered in determining the final version of these guidances, they are not individually addressed in this notice. The agency welcomes questions from interested parties regarding the practical application of these guidances. Specific questions should be directed to the appropriate persons within the agency who address advertising and promotion issues for the particular regulated product. (See contact persons above.)

One comment suggested that sponsors should not be allowed to use reprints or reference texts as a tool to promote unapproved uses of their products. The agency does not intend for these materials to be used in this way. Upon consideration, the agency has determined that an additional ''circumstance'' should be added to the