(ELA) to the Center for Biologics Evaluation and Research'' (63 FR 29741, June 1, 1998); (2) ''Electronic Submissions of Case Report Forms (CRF's), Case Report Tabulations (CRT's), and Data to the Center for Biologics Evaluation and Research'' (63 FR 29739, June 1, 1998); (3) ''Pilot Program for Electronic Investigational New Drug Applications (eIND) for Biological Products'' (63 FR 29740, June 1, 1998); and (4) ''Instructions for Submitting Lot Release Protocols to the Center for Biologics Evaluation and Research'' (63 FR 29742, June 1, 1998).

As part of agency efforts to harmonize the procedures for making electronic submissions, FDA has decided to combine certain information from the CDER and CBER guidances into this guidance on general considerations common to all submission types. The agency has considered received comments on the CDER and CBER guidances as it finalized this guidance document. Because of the ever changing nature of electronic submission technology and the need, for now, to recognize existing differences in CDER and CBER systems, the agency has decided to maintain separate guidances on CDER's NDA submissions and CBER's marketing application submissions. The agency will harmonize the concepts in the guidances to the extent our electronic systems permit.

Subsequent guidances on other submission types will be issued as they are developed. Consistent with the agency's Good Guidance Practices (62 FR 8961, February 27, 1997), guidances will be issued first in draft for comment, then revised and issued in final. This final guidance incorporates information from the earlier draft CDER and CBER documents and takes into account comments received on them.

As in the past, applicants planning to make submissions in the electronic format should consult public Docket No. 92S–0251 to determine which agency units are prepared to receive electronic submissions and the specific types of documents that can be submitted in electronic format.

This guidance document represents the agency's current thinking on general considerations for providing regulatory submissions in electronic format. 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.

Interested persons may submit written comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests are to be identified with the docket number found in the brackets in the heading of this document. The guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 22, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–2059 Filed 1–27–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1266]

Draft Guidance for Industry on Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling.'' The draft guidance is intended to clarify for prescription drug manufacturers, relabelers, and distributors FDA's position regarding placing the therapeutic equivalence code on approved FDA product labels and labeling. It also provides recommendations on how to display therapeutic equivalence codes on labels and labeling. Inclusion of a therapeutic equivalence code on prescription drug labels/labeling is voluntary.

DATES: Written comments may be submitted by March 29, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jerry Phillips, Center for Drug Evaluation and Research (HFD–610), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3225.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling.'' With the repeal of section 301(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(l)) as part of the Food and Drug Administration Modernization Act of 1997, FDA believes that it is legally permissible to allow therapeutic equivalence codes to be placed on drug product labels and labeling. The agency also believes that the use of therapeutic equivalence codes will contribute to the accurate and safe selection of generic products by pharmacists. This draft guidance is intended to: (1) Provide a historical perspective on therapeutic equivalence, (2) describe the process by which the agency advises the public on the therapeutic equivalence of approved drug products, and (3) advise manufacturers, relabelers, and distributors of the preferred format and placement of such information on product labels. Although inclusion of a therapeutic equivalence code on prescription drug labels/labeling normally is voluntary, in certain cases where safety issues are raised, the agency may ask that a code be included.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on placing the therapeutic equivalence code on the labeling of prescription drug products. 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.

Interested persons may, on or before March 29, 1999, submit to the Dockets Management Branch (address above) written comments on the draft guidance. 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. The draft guidance and received comments may be seen in the

office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 21, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–2015 Filed 1–27–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0249]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New collection; Title of Information Collection: Hospice Cost Report and Supporting Regulations in 42 CFR 413.20, and 413.24; Form No.: HCFA–R–0249 (OMB# 0938-new); Use: Medicare certified hospice programs must file an annual cost report with HCFA. This report contains information on overhead costs, assets, depreciation, and compensation which will be used for hospice rate evaluations.; Frequency: Annually; Affected Public: Not-for-profit institutions, and Business or other for-profit; Number of Respondents: 1,720; Total Annual Responses: 1,720; Total Annual Hours: 302,720.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 19, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–2028 Filed 1–27–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–8003]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Home and Community-Based Services Waiver Requests and Supporting Regulations in 42 CFR 440.180, and 441.301–441.310; *Form No.:* HCFA–8003 (OMB# 0938–0449); *Use:* Under a Secretarial waiver, States may offer a wide array of home and community-based services to individuals who would otherwise require institutionalization. States requesting a waiver must provide certain assurances, documentation and cost & utilization estimates which are reviewed, approved and maintained for the purpose of identifying/verifying States' compliance with such statutory and regulatory requirements. The purpose of this request is to provide authority for the State to furnish such individuals with services in the home and community-based setting; *Frequency:* When a State requests a waiver or amendment to a waiver; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 50; *Total Annual Responses:* 128; *Total Annual Hours:* 7,860.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: January 19, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–2029 Filed 1–27–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Draft Compliance Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice and comment period.

SUMMARY: This **Federal Register** notice seeks the comments of interested parties