availability of a draft guidance pertaining to General/Specific Intended use in the **Federal Register** of May 22, 1998 (63 FR 28392). The agency received two comments on the draft guidance. FDA has reviewed the comments and has made some revisions to the guidance in response to the comments.

II. Significance of Guidance

This guidance document represents the agency's current thinking on General/Specific Intended Use. 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 applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Guidance for Industry on General/Specific Intended Use'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 499 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''Guidance for Industry on General/Specific Intended Use,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

IV. Comments

Interested persons may, at any time, submit written comments regarding this final guidance to the contact person. Such comments will be considered when determining whether to amend the current guidance.

Dated: October 28, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–29567 Filed 11–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0729]

Draft ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer–Disinfectors;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer–Disinfectors.'' This draft guidance is not final nor is it in effect at this time. FDA recognizes the importance of providing applicants and other interested parties the agency's 510(k) submission criteria for washers and washer-disinfectors intended to process reusable medical devices. The intent of this draft guidance is to provide specific directions regarding information and data which should be submitted to FDA in 510(k) submission for these types of devices. This draft guidance is posted on the Internet and will be included in the panel package for the formal classification of these devices at the General Hospital and Personal Use Devices Panel meeting on September 14, 1998.

DATES: Written comments concerning this guidance must be received by February 3, 1999.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer–Disinfectors'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Written comments concerning this guidance must be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit written comments on ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer–Disinfectors'' to the contact person listed below. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION:

I. Background

Washers and washer-disinfectors intended for cleaning and disinfection of reusable medical devices, such as stainless steel devices, surgical instruments, including devices with lumens, respiratory therapy equipment, and other medical devices, were legally marketed devices prior to the enactment of the Medical Device Amendments of 1976. These devices are considered ''unclassified'' medical devices. On June 2, 1998, FDA published on the Internet a guidance document entitled ''CDRH Guidance Document for Washers and Washer–Disinfectors Intended for Processing Reusable Medical Devices'' to provide direction to the regulated industry on when a premarket notification [510(k)] submission is required for these unclassified washers and washer-disinfectors. In the ''CDRH Guidance Document for Washers and Washer–Disinfectors Intended for Processing Reusable Medical Devices,'' the agency made the commitment to provide industry with guidance on the information and data which should be included in a 510(k) submission. This draft guidance entitled ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer–Disinfectors'' provides regulated industry with specific guidance on the information and data that should be included in a 510(k) submission for these devices.

These unclassified washers and washer-disinfectors will undergo formal classification at the September 14, 1998, General Hospital and Personal Use Devices Panel meeting.

II. Significance of Guidance

This draft guidance represents the agency's current thinking on the

information and data which should be included in a 510(k) submission for the washers and washer-disinfectors intended to process reusable medical devices. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer–Disinfectors'' via your fax machine, call the CDRH Facts–On–Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 1252 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer–Disinfectors,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. ''Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer–Disinfectors'' will be available at ''http://www.fda.gov/cdrh/ode/Ed☒dn.HTML''.

IV. Comments

Interested persons may, on or before February 3, 1999, submit to Dockets Management Branch (address above) written comments regarding this 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 8, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–29565 Filed 11–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Collection # HCFA-R–265]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

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 (DHSS), has submitted to the Office of Management and Budget (OMB) the following request for Emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 C.F.R. Part 1320. We cannot reasonably comply with the normal clearance procedures because of the statutory requirement to implement section 4016 of Balanced Budget Act of 1997.

We are requesting OMB review and approval of this collection within 11 working days, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individual designated below, within 10 working days of the publication of this notice in the **Federal Register**. During this 180-day period HCFA will pursue OMB clearance of this collection as stipulated by 5 C.F.R. section 1320.5.

In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comments on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection summarized and discussed below.

Type of Information Collection Request: New collection;

Title of Information Collection: Medicare Coordinated Care Demonstration Project and Request for Information on Potential Best Practices of Coordinated Care;

Form/Collection No.: HCFA-R–265;

Use: Section 4016 of the Balanced Budget Act of 1997 (Public Law 105–33) requires the Secretary of Health and Human Services (the Secretary) to evaluate best practices in the private sector for methods of coordinated care. The statute also directs the Secretary to design a demonstration project for the Medicare fee-for-service population based on such evaluation.

The purpose of the demonstration is to evaluate models of coordinated care that improve the quality of services provided to beneficiaries who have a chronic illness and reduce expenditures under Parts A and B of the Medicare program.

We competitively awarded a task order to Mathematica Policy Research, Inc. (MPR) to conduct a review of best practices in coordinating care and provide a recommendation of demonstration design options. We will perform the final assessment of best practices and select the demonstration design.

We will publish a notice to announce our intent to conduct the Medicare Coordinated Care Demonstration and inform interested parties of the opportunity to submit information on potential best practices of coordinated care, as well as comment on potential aspects of the overall demonstration. We will solicit information on successful models of coordinated care, disease management, or case management that are appropriate for the Medicare fee-for-service population.

In the notice we will request that any person or organization submit information about successful programs; however, the information must provide evidence of success in sufficient detail to be useful. Thus, operators of programs may be in the best position to submit information regarding their approach. We are interested in the following items of information: