concentrate standard, and assays based on vWF plasma standards may not be appropriate to measure the potency of concentrates; and published clinical trials have not correlated the dosage of specific products with clinical outcome. The main goal of this workshop is to address these concerns through exchange of information about each of these issues, through the participation of the patient, industrial, medical, scientific, and regulatory communities. Workshop participants are asked to present their positions, rationales, and/or experiences regarding: (1) The benefits and liabilities of using ristocetin cofactor activity, or other tests, to measure vWF activity; (2) proposals for standardizing the potency and dosage of vWF concentrates; and (3) clinical trials to relate given dosage regimen to clinical benefit. Information presented at this workshop will assist in product development and facilitate licensure of safe and effective vWF products.

Registration and Requests for Oral Presentations: Fax registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by September 19, 1997. Registration at the site will be done on a space available basis on the day of the workshop beginning at 7:30 a.m. There is no registration fee for the workshop.

If you need special accommodations due to a disability, please contact Joseph Wilczek at least 7 days in advance.

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the workshop at a cost of 10 cents per page.

Dated: August 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–22982 Filed 8–27–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0201]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Evaluation of Proposed OTC Label Formats'' (study A) and ''OTC Label Format Preference'' (study B) has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 23, 1997 (62 FR 28482), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507) and 5 CFR 1320.12 , which provides for emergency processing of the proposed collection of information. OMB has approved the information collection and has assigned OMB control number 0910–0343. The approval expires on November 30, 1997. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Dated: August 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–22981 Filed 8–27–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0349]

Convenience Kits Interim Regulatory Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Convenience Kits Interim Regulatory Guidance.'' The guidance is final and in effect at this time. This guidance applies to convenience kits and provides guidance regarding FDA's intent to exercise enforcement discretion with respect to premarket notification requirements under the Federal Food, Drug, and Cosmetic Act (the act), and describes FDA's intent to propose rulemaking to exempt certain convenience kits from premarket notification requirements. The guidance addresses the type of data needed by the Center for Devices and Radiological Health (CDRH) to decrease the number of 510(k) submissions for convenience kits, saving Office of Device Evaluation (ODE) review resources. The agency is inviting public comment on this guidance.

DATES: Submit written comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Convenience Kits Interim Regulatory Guidance'' to the Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance. Submit written comments on the guidance to the contact person listed below.

FOR FURTHER INFORMATION CONTACT: Heather Rosecrans, Office of Device Evaluation (HFZ–404), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance represents a final document that describes a new regulatory approach to be applied to convenience kits that could result in a decrease in the number of 510(k) submissions for these devices and, in so doing, will save FDA review resources.

Under section 510(k) of the act (21 U.S.C. 360(k)), first time marketers of devices must submit a premarket notification and obtain clearance for a device before it can be lawfully introduced into interstate commerce. Many convenience kits that have been subject to 510(k) review are comprised of legally marketed devices that are simply being assembled in kit form strictly for the ''convenience'' of the purchaser.

FDA believes that under certain circumstances, premarket clearance for convenience kits may not be necessary to ensure protection of the public health. Accordingly, FDA intends to propose rulemaking to exempt certain, specifically identified convenience kits from the requirement of premarket notification. Until such rule is in effect, FDA intends to exercise enforcement discretion regarding the requirement for

premarket clearance for convenience kits that have intended uses, components, and processing methods that are described in the guidance, and where the assembler/manufacturer is able to reasonably conclude that any further processing of the kit and its components does not significantly affect the safety or effectiveness of any of its components. The intent to exercise enforcement discretion means that FDA does not intend to take enforcement action for the failure to submit premarket notification for convenience kits described in the guidance. In the future, FDA intends to propose rulemaking to formally exempt these types of kits from the requirement of premarket notification.

This guidance is effective immediately.

The ''Convenience Kits Interim Regulatory Guidance'' represents the agency's current thinking on premarket notification regulatory strategy for convenience kits. 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.

II. Electronic Access

In order to receive the ''Convenience Kits Interim Regulatory Guidance'' document 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 the second voice prompt press 2, and then enter the document number 562 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 do so by using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. The CDRH home page is updated on a regular basis and includes the ''Convenience Kits Interim Regulatory Guidance'' document, 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''. The ''Convenience Kits Interim Regulatory Guidance'' is available on the medical device reporting page at ''http://www.fda.gov/cdrh/ode/convkit.html''.

A text only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select MEDICAL DEVICES AND RADIOLOGICAL HEALTH. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

III. Request for Comments

Interested persons may, at any time, submit to the contact person listed above written comments regarding this guidance.

Dated: August 21, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–22855 Filed 8–27–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–R–39]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 the 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.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Home Health Medicare Conditions of Participation (COP) Information Collection Requirements (ICR's) as outlined in Regulation 42 CFR Part 484; *Form No.:* HCFA–R–39 OMB #0938–0365; *Use:* The ICR's contained in 42 CFR part 484 outline Home Health Agencies Medicare COP's to ensure Home Health Agencies meet Federal patient health and safety requirements. *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions and Federal Government; *Number of Respondents:* 10,203; *Total Annual Responses:* 10,203; *Total Annual Hours:* 86,008.

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection for which approval has expired; *Title of Information Collection:* Negative Case Action Review Process (NCA)/Annual Report and Supporting Regulations 42 CFR 431.800; *Form No.:* HCFA—6401 OMB #0938–0300; *Use:* HCFA uses the NCA reviews conducted by states to assure that beneficiaries are not being denied medical assistance that they are eligible for and that recipients are being given adequate and timely notice of termination. The results of NCA reviews are used by states and the Federal Government to identify problem areas and plan corrective action initiatives. *Frequency:* Annually; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 51; *Total Annual Responses:* 51; *Total Annual Hours:* 6,770.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, 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 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.