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]

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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