every exemption request is grossly out of proportion to the minimal increment in protection of the environment that may be gained. The comment proposed an alternative approach whereby an EA would be required only in extraordinary circumstances (i.e., where significant adverse environmental impacts may occur that are not subject to regulation by other authorities).

The comment did note that FDA had published a proposed rule (National Environmental Policy Act (NEPA): Proposed Revision of Policies and Procedures; in the **Federal Register** of April 3, 1996 (61 FR 14922); republished May 1, 1996 (61 FR 19476), that would eliminate the requirement for EA's for certain types of actions resulting from requests for exemption from regulation as a food additive under § 170.39 and that would also eliminate the requirement for information on possible environmental effects at the sites of manufacture of all FDA-regulated substances. This comment, submitted by a trade association, noted that the association also submitted a comment to the agency on the proposed NEPA rule. The association's comment on the proposed NEPA rule is essentially identical to the present comment outlined in the preceding paragraph.

In the **Federal Register** of July 29, 1997 (62 FR 40570), the agency published a final rule revising its NEPA policies and procedures (''the final NEPA rule''). The final NEPA rule was issued after the agency reviewed and addressed the comments received on its April 3, 1996, proposed rule, including the comment submitted by the trade association, summarized previously.

As discussed in detail in the preamble to the final NEPA rule (62 FR 40579 through 40581), the agency agreed in part with the comment and expanded the scope of actions included in two categorical exclusions § 25.32(i) and (j) (21 CFR 25.32(i) and (j)), including actions on requests for exemption from regulation under § 170.39. However, as further discussed in the preamble to the final NEPA rule, the agency did not agree completely with this comment. Specifically, FDA concluded that certain classes of actions on food-contact materials should continue to require EA's and that the preparation of EA's for requests for these actions is not unduly burdensome for the industry. The § 170.39 exemption requests that continue to require an EA are, for the most part, for actions on substances present at greater than 5 percent of finished food-packaging materials that are not components of coatings and for actions on substances present at 5 percent or less of finished food-packaging materials that are not expected to remain with finished food-packaging materials through use by consumers. As the agency explained in the preamble to the final NEPA rule, actions on these types of substances have the potential for significant environmental impact, and such potential can be evaluated only by the agency's review of EA's prepared by requesters. In accordance with 21 CFR 25.21, EA's are also required for those actions where extraordinary circumstances indicate that there may be significant environmental effects, even though the actions belong to a class that ordinarily would warrant exclusion from the requirement to prepare an EA. Guidance on preparing EA's is available from the Food and Drug Administration's Office of Premarket Approval (HFS–200), 200 C St. SW., Washington, DC 20204.

In addition to the review summarized previously that resulted in the agency expanding the scope of two categorical exclusions (§ 25.32(i) and (j)), the agency has also reviewed the types of uses of food-contact articles that have been the subject of exemption requests received since the threshold of regulation process was implemented on August 16, 1995. The agency estimates that the percentage of uses that will qualify for categorical exclusion under the agency's revised NEPA regulations may be as high as 8 percent. It is further estimated that those exemption requests that qualify for categorical exclusions will require, on average, 48 h to prepare as opposed to the 88 h typically required to prepare exemption requests that include an EA. This would represent a 45 percent reduction in paperwork burden for such requests. The overall paperwork burden associated with the threshold of regulation process would also decrease dramatically. Prior to implementation of the amended NEPA regulations, the annual industry burden associated with threshold of regulation exemption requests was estimated to be 5,280 h based on the assumption that the agency receives 60 requests per year and that each request requires on average 88 h to prepare. If, as projected, 87 percent of threshold of regulation exemption requests qualify for the categorical exclusions discussed previously, it is estimated that the overall paperwork burden would decrease to 3,200 h (52 requests x 48 h + 8 requests x 88 h). This would represent a 39 percent overall reduction in paperwork burden.

2. One comment asserted that the requirement that a manufacturer of a substance submit an exemption from regulation request to FDA is not necessary for the proper performance of FDA's functions. Instead, the comment argued that manufacturers should be able to make their own determination as to whether the use of a substance in a food contact article meets the criteria for exemption set out in § 170.39. The comment further asserted that allowing self-determinations of exemption status would substantially reduce the burden on industry.

FDA disagrees with this comment for several reasons. In the preamble to the final rule issuing § 170.39, the agency responded in detail to comments recommending that manufacturers be permitted to determine themselves whether use of a substance is entitled to an exemption from the food additive listing regulation requirement (60 FR 36582 at 36586 through 36587. In that response, the agency explained that under *Monsanto* v. *Kennedy*, 613 F. 2d 947 (D.C. Cir. 1979), only the Commissioner of Food and Drugs has the authority to exempt a substance from regulation as a food additive. The agency's response also discussed in detail the policy rationale underlying the procedure in § 170.39 (i.e., that a process wherein the agency determines which substances will be exempt from regulation as food additives will be binding on the agency and will ensure more consistent exemption decisions). For the same reasons discussed in the preamble to the final rule, FDA concludes that this comment does not provide a basis for altering the information collection requirements of § 170.39.

Dated: December 24, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–086 Filed 1-2-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0374]

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 ''Latex Condoms; User Labeling; Expiration Dating'' has been approved

by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 26, 1997 (62 FR 50497), 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). 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. OMB has now approved the information collection and has assigned OMB control number 0910–0352. The approval expires on November 30, 2000.

Dated: December 23, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–075 Filed 1-2-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0506]

Commercialization of In Vitro Diagnostic Devices (IVD's) Labeled for Research Use Only or Investigational Use Only; Draft Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft Compliance Policy Guide (CPG) entitled ''Commercialization of In Vitro Diagnostic Devices (IVD's) Labeled for Research Use Only or Investigational Use Only.'' The purpose of the CPG is to provide guidance on FDA's enforcement priorities concerning investigational or research IVD's that are being commercialized for diagnostic or prognostic purposes.

DATES: Written comments on the draft CPG may be submitted by April 6, 1998.

ADDRESSES: Submit written comments on the draft CPG to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written requests for single copies of the draft CPG to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (CDRH) (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850 (301–443–6597 or outside MD 1–800–638–2041). Send two self-addressed adhesive labels to assist that office in processing your requests, or FAX your request to 301–443–8818. Facsimiles of the draft CPG are available from the Division of Small Manufacturers Assistance, CDRH. To receive the draft CPG on your fax machine, call the CDRH Facts-On-Demand system at 1–800–899–0381 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, ''671,'' followed by the pound sign, ''#''. Follow the remaining voice prompts to complete the request. Copies of the draft CPG may also be downloaded to a personal computer with access to the World Wide Web (www). The Office of Regulatory Affairs (ORA) and CDRH Home Pages include the draft CPG and may be accessed at ''http://www.fda.gov/ora'' or ''http://www.fda.gov/cdrh'' respectively. The draft CPG will be available on the Compliance References or Compliance Information pages for ORA and CDRH respectively.

FOR FURTHER INFORMATION CONTACT: Betty W. Collins, Office of Compliance (HFZ–300), Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4588, ext. 165.

SUPPLEMENTARY INFORMATION: FDA has developed a draft CPG to provide guidance on FDA's enforcement priorities concerning investigational or research IVD's that are being commercialized for diagnostic or prognostic purposes. This draft CPG applies to IVD's sold or distributed as test kits. Many manufacturers of IVD's have not followed the requirements set forth in parts 809 and 812 (21 CFR parts 809 and 812). As a result, numerous IVD's labeled for research or investigational purposes are being promoted, distributed, and used for commercial purposes. This has resulted in the widespread use of laboratory tests with unproven performance characteristics. Unless exempted from the requirement to submit premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(k)), IVD's that are commercially distributed for diagnostic use prior to FDA approval or clearance are adulterated and misbranded under sections 501(f)(1)(B) and 502(o) of the act (21 U.S.C. 351(f)(1)(B) and 352(o)). Such distribution subjects the devices and responsible firms to regulatory action.

However, FDA recognizes that certain improperly commercialized IVD's have been in extensive clinical use for a significant period of time. FDA further recognizes that immediate regulatory action against certain IVD's might result in adverse consequences to individual patients and the public health. Therefore, FDA has prepared a draft CPG in order to describe its enforcement policy. Except in specified instances, FDA does not intend to initiate enforcement action, for 18 to 30 months from the **Federal Register** publication date of the notice of availability (NOA) for the final CPG on commercialization of IVD's labeled for research use only or investigational use only, against IVD's that have not been approved or cleared, provided the IVD manufacturers, importers, and distributors take steps and obtain FDA approval of a premarket approval application, product license application, or clearance of a premarket notification submission under section (510(k)) of the act during that time period. Those steps include undertaking, by 6 months from the **Federal Register** publication date of the NOA for the final CPG, any necessary clinical investigations or other studies under a protocol sufficient to allow determination of the IVD's safety and effectiveness. FDA believes that the 18- to 30-month time period is a reasonable period for gathering safety and effectiveness data and obtaining FDA approval or clearance. This draft CPG applies to IVD's that are regulated by FDA's CDRH and Center for Biologics Evaluation and Research, and supersedes FDA's earlier draft made public in June 1996.

This draft CPG does not cover analyte specific reagents (ASR's) that, as specified under §§ 809.10(e), 809.30, and 864.4020 (21 CFR 864.4020), are not labeled or promoted with performance claims, and are sold to: (1) In vitro diagnostic manufacturers; (2) clinical laboratories regulated under the Clinical Laboratory Improvement Amendments of 1988 as qualified to perform high complexity testing under 42 CFR part 493 or clinical laboratories regulated under the Veterans Health Administration Directive 1106; and (3) organizations that use the ASR to make tests for purposes other than providing diagnostic information to patients and practitioners. ASR's are defined as