Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–7651, *Juanmanuel.vilela@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. This document solicits comments on certain labeling requirements for blood and blood components, including Source Plasma, finalized as part of a rule FDA is publishing elsewhere in this **Federal Register** entitled ''Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma.''

Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma—(OMB Control Number 0910–NEW)

FDA is finalizing the labeling requirements for blood or blood components intended for use in transfusion or for further manufacture pursuant to the provisions of the Public Health Service Act (PHS Act) (42 U.S.C. 262–264), and the drugs, devices, and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351–353, 355, 360, 360j, 371, and 374). Under these provisions of the PHS Act and the Federal Food, Drug, and Cosmetic Act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, potent, and properly labeled, and to prevent the introduction, transmission, and spread of communicable disease.

Under this rulemaking, FDA is consolidating the regulations related to labeling blood and blood components. Regulations for labeling of blood and blood components will be consolidated into § 606.121 (Container label) (21 CFR 606.121) and 21 CFR 606.122 (Circular of information). This notice solicits comments on the information collection associated with § 606.121(c)(11) (21 CFR 606.121(c)(11)) which requires that if the product is intended for further manufacturing use, a statement listing the results of all the tests for communicable disease agents required under § 610.40 (21 CFR 610.40) for which the donation has been tested and found negative must be on the container label; except that the label for Source Plasma is not required to list the negative results of serological syphilis testing under § 610.40(i) (21 CFR 610.40(i)) and § 640.65(b) (21 CFR 640.65(b)). In addition, this notice also solicits comments on the information collection associated with § 606.121(e)(2)(i) (21 CFR 606.121(e)(2)(i)) which requires that the product labels of certain red blood cells must include the type of additive solution with which the product was prepared.

The Agency believes the rule amendments and the information collection provisions under § 606.121(c)(11) and § 606.121(e)(2)(i) in the final rule are part of usual and customary business practice and do not create any new burden for respondent.

The collection of information requirements under §§ 606.121 and 606.122 are approved under OMB control number 0910–0116; and those in 21 CFR 640.70 have been approved under OMB control number 0910–0338. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: December 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–33555 Filed 12–29–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0619]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices: Humanitarian Use Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 30, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: (202) 395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0332. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–5156, *Daniel.Gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices: Humanitarian Use Devices—(OMB Control Number 0910–0332)—Extension

This collection of information implements the humanitarian use device (HUD) provision of section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m)) and subpart H, part 814 (21 CFR part 814). Under section 520(m) of

the FD&C Act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless an exemption is granted because there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose the disease or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury with the probable benefit to health from using the device outweighing the risk of injury or illness from its use. This takes into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2) exempt an HUD from the effectiveness requirements under sections 514 and 515 of the FD&C Act, provided that the device meets requirements set forth under section 520(m) of the FD&C Act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of an HUD is in compliance with the HUD provisions under section 520(m) of the FD&C Act.

The number of respondents in tables 1 and 2 of this document are an average from data for the previous 3 years, *i.e.,* fiscal years 2008 to 2010. The number of annual reports submitted under section 814.126(b)(1) in table 1 reflects 43 respondents with approved HUD applications. Likewise, under section 814.126(b)(2) in table 2, the number of recordkeepers is 43.

In the **Federal Register** of September 7, 2011 (76 FR 55394), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
814.102	17	1	17	40	680
814.104	5	1	5	320	1,600
814.106	5	5	25	50	1,250
814.108	47	1	47	80	3,760
814.116(e)(3)	3	1	3	1	3
814.124(a)	22	1	22	1	22
814.124(b)	12	1	12	2	24
814.126(b)(1)	43	1	43	120	5,160
Total					12,499

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeeper	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
814.126(b)(2)	43	1	43	2	86

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 27, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–33551 Filed 12–29–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0555]

Determination That HYCODAN (Hydrocodone Bitartrate and Homatropine Methylbromide) Tablets, 5 Milligrams/1.5 Milligrams, and HYCODAN (Hydrocodone Bitartrate and Homatropine Methylbromide) Oral Solution, 5 Milligrams/5 Milliliters and 1.5 Milligrams/5 Milliliters, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that HYCODAN (hydrocodone bitartrate and homatropine methylbromide) tablets, 5 milligrams (mg)/1.5 mg, and HYCODAN (hydrocodone bitartrate and homatropine methylbromide) oral solution, 5 mg/5 milliliters (mL) and 1.5 mg/5 mL, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for hydrocodone bitartrate and homatropine methylbromide tablets, 5 mg/1.5 mg, and HYCODAN (hydrocodone bitartrate and homatropine methylbromide) oral solution, 5 mg/5 mL and 1.5 mg/5 mL, if all other legal and regulatory requirements are met.