Sciences and Engineering, NIOSH, CDC, 4676 Columbia Parkway, M/S R–5, Cincinnati, Ohio 45226, telephone 513/841–4292.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: July 9, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 99–18293 Filed 7–16–99; 8:45 am]

BILLING CODE 4160–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2097]

Agency Information Collection Activities: Proposed Collection; Comment Request; Medical Devices; Humanitarian Use Devices

AGENCY: Food and Drug Administration, HHS.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for Humanitarian Use Devices, 21 CFR part 814 subpart H.

DATES: Submit written comments on the collection of information by September 17, 1999.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–26; Rockville, MD 20857, 301–827–1223.

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. A 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, including each proposed extension of an existing 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: (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.

Medical Devices; Humanitarian Use Devices—21 CFR Part 814—Subpart H (OMB No. 0910–0332—Extension)

This collection implements the humanitarian use device (HUD) provision under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(m)) and 21 CFR part 814 subpart H. Under section 520(m) of the act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnosis 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 the exemption is granted, and there is no comparable device, other than another HUD approved under this exemption, available to treat or diagnosis the disease or condition; and (3) the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The information collection herein will allow FDA to determine whether to: (1) Grant HUD designation of a medical device, (2) exempt a HUD from the effectiveness requirements in sections 514 and 515 of the act provided that the device meets requirements set forth in section 520(m) of the act, and (3) grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making these determinations. Also, this information enables FDA to determine whether the holder of a humanitarian device exemption (HDE) is in compliance with the HDE requirements.

Description of Respondents: Businesses or others for-profit.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMANITARIAN DEVICE EXEMPTION SPONSORS[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.102	20	1	20	40	800
814.104(b) and 814.104(c)	15	1	15	320	4,800
814.106	15	4	60	50	3,000
814.108	12	1	12	80	960
814.116(d)(3)	1	1	1	1	1
814.124(a)	5	1	5	1	5
814.124(b)	1	1	1	2	2
814.126(b)(1)	15	1	15	120	1,800

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMANITARIAN DEVICE EXEMPTION SPONSORS[1]—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total					11,368

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMANITARIAN DEVICE EXEMPTION SPONSORS[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
814.126(b)(2)	15	1	15	2	30
Total					30

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

A. Explanation of Report Burden Estimate:

Generally, the information requested from respondents represents an accounting of information already in the possession of the applicant.

In the original publication in the **Federal Register** of the final rule for HUD's on June 26, 1996, FDA based its estimates on comments received to the proposed rule, industry contact, and internal FDA benchmark factors (such as the number of PMA's processed). The numbers generated in the current estimate as shown in Tables 1 and 2 of this document and described in the following paragraphs, are based upon those prior estimates, and they have only been modified if actual numbers over the past 3 years have indicated a significantly different trend.

The first HUD rule became effective in fiscal year 1997, and FDA has only a few years of actual data to compare to original estimated numbers. Although actual numbers are less than the estimated numbers for this information collection, FDA believes that as manufacturers become more familiar with the program, FDA will experience a larger number of submissions under the provisions discussed as follows:

§ 814.102—It is estimated that 20 sponsors per year will submit a request for HUD designation. It is estimated to require 40 staff hours to complete each HUD designation request.

§ 814.104—FDA estimates 15 sponsors per year will submit an HDE application after receiving HUD designation. FDA estimates that it will require an average of 320 staff hours to complete each HDE application. § 814.110(a) requires that a new indication for use of a HUD approved under this part be submitted as a new HDE application complying with § 814.104. All burden under this section is included under the estimate for § 814.104.

§ 814.106—It is estimated that 4 times per year FDA will request or the sponsor will submit additional information or resubmit an HDE or HDE supplement for approximately 15 of the submitted HDE applications. FDA estimates that it will require the respondents to take an average of 50 staff hours to complete each amendment or resubmitted application. If the FDA refuses to file the HDE application, requests for an informal conference (under § 814.112(b)) will be processed as an HDE amendment. Responses to approvable and not approvable letters (§ 814.116(b), (c), and (d)) will be processed as HDE amendments. A request for an opportunity for an informal hearing, prior to FDA issuing an order withdrawing approval, under § 814.118(d), will be processed as an HDE amendment. Because FDA only tracks amendments, and not the reasons for the amendment, the burden estimates for the sections listed in the Tables 1 and 2 of this document are included in the burden estimate for § 814.106.

§ 814.108—FDA anticipates that it will receive approximately 12 supplements for the submitted HDE applications. It is estimated that it will take approximately 80 staff hours to complete each supplemental application.

§ 814.116(d)(3)—FDA believes that it will receive approximately 1 request to withdraw an HDE application per year, based on withdrawals submitted in FY 1997 and FY 1998. FDA estimates it will take no longer than 1 staff hour to complete each written withdrawal notice.

§ 814.124(a)—FDA anticipates that 5 physicians will use HUD's in emergency situations before obtaining institute and review board (IRB) approval. FDA estimates that notification under this section will take an average of 1 hour per response.

§ 814.124(b)—FDA anticipates that one holder of an approved HDE will notify FDA of IRB withdrawal of approval. FDA estimates that it will take an average of 2 staff hours to notify FDA of IRB withdrawal.

§ 814.126(b)(1)—Following FDAMA, § 814.126 was amended to incorporate section 520(m)(5) of the act (21 U.S.C. 360j), which provides FDA the authority to require an HDE applicant to demonstrate continued compliance with the HDE requirements, if the agency believes that such a demonstration is necessary to protect the public health or has reason to believe that the criteria for the HDE exemption are no longer met. FDA amended this section to delete the requirement of an annual report and to include instead a periodic reporting requirement that will be established by the approval order for the HDE. This provision permits the agency to obtain sufficient information for it to determine whether there is reason to question the continued exemption of the device from the act's effectiveness requirements.

FDA anticipates that because of this amendment, the 15 HDE holders will remain active and therefore, estimates that 15 periodic reports will be received. FDA also estimates that it will take an average of 120 staff hours to complete a periodic report as a result of this amendment.

B. Explanation of Recordkeeping Burden Estimate:

§ 814.126(b)(2)—FDA anticipates that 15 HDE holders per year will maintain records of certain required information. It is estimated that it will take an average of 2 staff hours to maintain this information.

Dated: July 12, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–18234 Filed 7–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1833]

SoloPak Laboratories, Inc.; Withdrawal of Approval of 1 New Drug Application and 38 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 21, 1999 (64 FR 33097). The document announced the withdrawal of approval of 1 new drug application (NDA) and 38 abbreviated new drug applications (ANDA's) held by SoloPak Laboratories, Inc. The document omitted language explaining that the sponsor voluntarily removed the products from the market because of discrepancies concerning the data submitted to support continued approval of the applications. This document corrects that omission.

EFFECTIVE DATE: JULY 19, 1999.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

In FR Doc. 99–15581, appearing on page 33097 in the **Federal Register** of Monday, June 21, 1999, the following correction is made: Onpage 33098, immediately preceding the table, add the following two paragraphs to read as follows:

Recently, FDA became aware of discrepancies concerning the data submitted to support continued approval of the following ANDA's held by SoloPak:

ANDA 88–457; Heparin Lock Flush Solution USP, 10 units/milliliter (mL); and

ANDA 88–519; Phenytoin Sodium Injection USP, 50 milligrams (mg)/mL.

After careful review of inspectional findings, the agency determined that there was sufficient justification to initiate proceedings to withdraw approval of the two products listed above. SoloPak was notified in writing of the determinations and, in accordance with § 314.150(d) (21 CFR 314.150(d)), was offered an opportunity to permit FDA to withdraw the applications. Subsequently, in letters dated December 15, 1998, and March 31, 1999, SoloPak requested withdrawal under § 314.150(d) of the applications listed in the following table, thereby waiving its opportunity for a hearing.

Dated: July 8, 1999.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–18235 Filed 7–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 6, 1999 (64 FR 36361). The document announced that FDA is being restructured to create a more streamlined and efficient Office of the Commissioner that will provide leadership without compromising programmatic effectiveness. The restructuring document, which became effective on June 20, 1999, was published with an inadvertent error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

In FR Doc. 99–17019, appearing on page 36361 in the **Federal Register** of Tuesday, July 6, 1999, the following correction is made:

1. On page 36362, in the first column, in the fourth paragraph, beginning in the twelfth line ''Center for Devices and Radiological Health'' is corrected to read ''Center for Drug Evaluation and Research.''

Dated: July 12, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–18236 Filed 7–16–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Availability of New E-mail Service for Government-Owned Inventions Available for Licensing and Cooperative Research Opportunities

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The Office of Technology Transfer (OTT), National Institutes of Health desires to announce the availability of a new e-mail service concerning government-owned inventions available for licensing and cooperative research opportunities.

OTT has initiated a Techbrief e-mail list service to inform companies, institutions and anyone interested in biomedical technology transfer about NIH and FDA technologies available for licensing, as well as Cooperative Research and Development (CRADA) opportunities with PHS scientists.

ADDRESSES: Persons may subscribe to the list at no charge upon request to: Dr. George Keller, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852 (telephone: (301) 496–7735, extension 246; fax: (301) 402–0220, e-mail: gk40j@nih.gov). Please include: company affiliation, title, address, phone and fax numbers, and e-mail address. A convenient form is available at the OTT web site: http://www.nih.gov/od/ott/.

Dated: July 12, 1999.

Jack Spiegel, PhD.,

Director, Division of Technology Development & Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 99–18373 Filed 7–16–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of