single database to more effectively carry out this matching program. In order for TMA to meet the requirements of current law, CMS agrees to disclose certain Part A and Part B enrollment data on this dual eligible population, which will be used to determine a beneficiary's eligibility for care under CHAMPUS/TRICARE. DEERS will receive the results of the computer match and provide the information to TMA for use in its matching program.

This computer matching agreement supersedes all existing data exchange agreements between CMS and DMDC applicable to the exchange of personal data for purposes of disclosing enrollment and eligibility information for MHS beneficiaries who are Medicare eligible.

CATEGORIES OF RECORDS AND INDIVIDUALS COVERED BY THE MATCH:

DEERS will furnish CMS with an electronic file on a monthly basis extracted from the DEERS' systems of records containing social security numbers (SSN) for all MHS beneficiaries who may also be eligible for Medicare benefits. CMS will match the DEERS finder file against its ''Medicare Beneficiary Database'' system of records (System No. 09–70–0536), and will validate the identification of the beneficiary and provide the Health Insurance Claim Number that matches against the SSN and date of birth provided by DEERS, and also provide the Medicare Part A entitlement status and Part B enrollment status of the beneficiary. CMS's data will help TMA to determine a beneficiary's eligibility for continued care under TRICARE. DEERS will receive the results of the computer match and provide the information provided to TMA for use in its program.

DESCRIPTION OF RECORDS TO BE USED IN THE MATCHING PROGRAM:

DoD will use the SOR identified as S322.50, entitled ''Defense Eligibility Records,'' at 69 **Federal Register** (FR) 33376 (June 15, 2004), as amended by 69 FR 67118 (November 16, 2004). SSNs of DoD beneficiaries will be released to CMS pursuant to the routine use set forth in the system notice, which provides that data may be released to HHS ''for support of the DEERS enrollment process and to identify individuals not entitled to health care.''

Identification and Medicare status of DoD eligible beneficiaries will be provided to TMA to implement the statutory program. Therefore, eligibility information may also be maintained in the SOR identified as DHA 07, entitled ''Military Health Information System (MHIS),'' at 70 FR 44574 (August 3, 2005).

The release of the data for CMS is covered under the ''Enrollment Database,'' System No. 09–70–0502 published in the **Federal Register** at 73 FR 10249 (February 26, 2008). Matched data will be released to DEERS pursuant to the routine use number 2 as set forth in the system notice.

INCLUSIVE DATES OF THE MATCH:

The Matching Program shall become effective no sooner than 40 days after the report of the Matching Program is sent to OMB and Congress, or 30 days after publication in the **Federal Register**, which ever is later. The matching program will continue for 18 months from the effective date and may be renewed for an additional 12 month period as long as the statutory language for the match exists and other conditions are met.

[FR Doc. E8–23080 Filed 9–30–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0499]

Agency Information Collection Activities; Proposed Collection; Comment Request; Implementation of Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the requirement established by Title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85) that device establishments must submit registration and listing information by electronic means, using FDA Form 3673, unless the Secretary of the Department of Health and Human Services (the Secretary) grants them a waiver from the electronic submission requirement.

DATES: Submit written or electronic comments on the collection of information by December 1, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (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: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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, 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 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.

Implementation of Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007 (OMB Control Number 0910–0625)—Extension

Sections 222, 223, and 224 of FDAAA, which were in effect on October 1, 2007, require that device establishment registrations and listings under section 510 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360), (including the submission of updated information), be submitted to the Secretary by electronic means, unless the Secretary grants a request for waiver of the requirement because the use of electronic means is not reasonable for the person requesting the waiver. FDA expects 20,000 to 30,000 device establishments to begin registering electronically at that time.

Section 222 of FDAAA amends sections 510(b) of the FD&C Act to require domestic establishments to register annually during the period beginning October 1 and ending December 31 of each year. Section 222 of FDAAA also amends section 510(i)(1) of the FD&C Act to require foreign establishments to register immediately upon first engaging in one of the covered device activities described under the statute, and in addition, they must also register annually during the time period beginning October 1 and ending December 31 of each year. Further, section 223 of FDAAA amends section 510(j)(2) of the FD&C Act to require establishments to list their devices with FDA annually, during the time period beginning October 1 and ending December 31 of each year.

Under FDAAA, device establishment owners and operators are required to keep their registration and device listing information up-to-date using the agency's new electronic system. Owners and operators of new device establishments must use the electronic system to create new accounts, new registration records, and new device listings. Section 224 of FDAAA amends section 510(p) of the FD&C Act by allowing an affected person to request a waiver from the requirement to register electronically when the ''use of electronic means'' is not reasonable for the person.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the 2007 Amendments	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
222[2]	3673	2,600	1	2,704	0.5	1,352
223[2]	3673	24,382	1	24,382	0.25	6,095
224[2]		29,370	1	29,370	0.75	22,028
224[3]		2,600	1	2,600	0.5	1,300
224 (waiver request)[2]		20	1	20	1	20
224 (waiver request)[3]		1	1	1	1	1
Total Hours						30,796

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One time burden.
[3] Annual increase in burden.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Section of the 2007 Amendments	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Hours
222[2]	33,490	1	29,900	.25	7,475
223[2]	16,524	4	66,096	.5	33,048
Total Hours					40,523

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

The estimates in Table 1 of this document are based on FDA's experience, data from the device registration and listing database, and our estimates of the time needed to complete the previously required forms. We estimate that the time needed to enter registration and listing information electronically using FDA Form 3673 will not differ significantly from the time needed to fill in the paper forms (FDA Forms 2891, 2891a, and 2892) that previously were used for this purpose because the information required is essentially identical.

In addition, under section 224 of FDAAA, device establishment owner/operators, for whom registering and listing by electronic means is not reasonable, may request a waiver from the Secretary. Because a device establishment's owner/operator is required to register and list, they would need only to have access to a computer, Internet and an e-mail address for registration and listing by electronic means, the agency did not anticipate receipt of a large number of requests for waiver. For the first few months of operation of the web-based system, from

the October through December 2007 timeframe, FDA received fewer than 10 requests for waivers for the requirement to submit registration and listing information electronically. As data for more than 16,000 establishments have been received electronically for the same period, these requests amount to less than 1 percent of the total number of establishments that have responded.

Based on information taken from our databases, FDA estimates that there are 29,370 owner/operators who collectively register a total of 33,490 device establishments. The number of respondents listed for section 224 of FDAAA in Table 1 of this document is 29,370, which corresponds to the number of owner/operators who annually register one or more establishments. In addition, FDA estimates that 4,988 owner/operators are initial importers who must register their establishments but who, under FDA's existing regulations, are not required to list their devices unless they initiate or develop the specifications for the devices or repackage or relabel the devices. The number of respondents included in Table 1 of this document for section 223 of FDAAA is 24,382, which corresponds to the number of owner/operators who annually list one or more devices (29,370 - 4,988 = 24,382).

To calculate the burden estimate for waiver requests under section 224 of FDAAA, we assume as stated previously, that less than one-tenth of 1 percent of the 33,490 total device establishments would request waivers from FDA. This means the total number of waiver requests would probably not exceed 20 requests (33,490 x 0.0006). We also estimate that the one-time burden on these establishments would be an hour of time for a mid-level manager to draft, approve, and mail a letter. In addition, FDA estimates the total number of establishments will increase by 2,600 new establishments each year. Of the 2,600 new registrants each year, we assume that less than 1 percent (i.e., 1) of these will also request waivers each year. The total, therefore, is 21 waiver requests, which could increase by only one additional request each year.

The burden estimate for recordkeeping requirements under section 222 of FDAAA in Table 2 of this document, complies with the requirement that owners or operators keep a list of officers, directors, and partners for each establishment. Owners or operators will need to provide this information only upon request from FDA. However, it is assumed that some effort will need to be expended for keeping such lists current.

The burden estimate for the recordkeeping requirements under section 223 of FDAAA in table 2 of this document reflect other recordkeeping requirements for devices listed with FDA, and the requirement to provide these records upon request from FDA. These estimates are based on FDA experience.

Dated: September 25, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–22989 Filed 9–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0512]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 collection of information, 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.

DATES: Submit written or electronic comments on the collection of information by December 1, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (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: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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, 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 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.

Medical Devices: Humanitarian Use Devices—21 CFR Part 814 (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 act) (21 U.S.C. 360j(m)) and subpart H, part 814 (21 CFR part 814). Under section 520(m) of the act, FDA is authorized to exempt a 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 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