

**SUPPORTING STATEMENT  
FOR  
Applications for Exemption from Preemption  
of Medical Device Requirements  
21 CFR 808.20, 21 CFR 808.25  
OMB Control Number 0910-0129**

**A. JUSTIFICATION**

The Food and Drug Administration (FDA) is requesting approval from the Office of Management and Budget for the information collection requirements contained in 21 CFR Part 808: Exemptions from Federal Preemption of State and Local Medical Device Requirements (Attachment A).

**1. Circumstances Making the Collection of Information Necessary**

Section 521(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k(a)) provides that no State or local government may establish, or continue in effect, any requirement with respect to a medical device that is different from, or in addition to, any Federal requirement applicable to the device. Section 521(b) (Attachment B) of the act permits FDA to exempt such a requirement from automatic preemption, following receipt of a written application from the State or local government involved, if the requirement is more stringent than the Federal requirement, or is necessitated by compelling local conditions, and would not cause the device to be in violation of any portion of the act.

The information collection requirements in 21 CFR 808 are as follows:

**21 CFR 808.20 - Reporting**

Any State or political subdivision may apply to FDA for an exemption from preemption for any requirement that it has enacted and that is preempted.

**21 CFR 808.25(d) -Reporting**

A State or political subdivision or any interested person may request an oral hearing on an application for exemption from preemption.

**2. Purpose and Use of the Information**

The information will be used by FDA to determine whether to grant an exemption from preemption. FDA will make this determination based on what is in the best interests of the public health within the criteria in section 521(b). Unless a State or local government applies for and receives an exemption from preemption, the State or local government may not enforce the preempted requirement.

**3. Use of Information Technology and Burden Reduction**

FDA is continuously seeking ways through advances in information technology to reduce burden hours. In the FEDERAL REGISTER of March 20, 1997 (62 FR 13430) (Attachment C), FDA issued a final regulation that, under certain circumstances, permits the agency to accept electronic records, electronic signatures, and handwritten signatures executed to electronic records as generally equivalent to paper records and handwritten signatures executed on paper. These regulations apply to records when submitted in electronic form that is called for in Title 21 of the Code of Federal Regulations. The use of electronic forms of reporting and record keeping submissions to FDA remains voluntary. The intended effect of the final regulation is to permit the use of electronic technologies in a manner that is consistent with FDA's overall mission and that preserves the integrity of the agency's enforcement activities. Applications for exemption from preemption may make use of any appropriate information technology.

Exemptions from preemption are filed by states, sent to the Dockets Management Branch, and are similar to citizen petitions. The Dockets Management Branch presently only accepts paper copies of the exemption filing because the exemption from preemption application requires a signature. FDA's Dockets Management Branch is currently developing, but has not finished, a system to accept an electronic signature document at this time. When the system is placed on-line, FDA will accept electronic exemption from preemption documents.

FDA is also examining all information collected by the Center to determine which submissions may be enhanced through the use of electronic submission. The Center for Devices and Radiological Health (CDRH) has formed an Electronic Submission Reengineering Task Force to examine these issues. Presently, the group is examining current electronic submission pilot programs, determining which documents are candidates for electronic submission, and prioritizing those documents. CDRH is also looking at media alternatives for electronic submission, such as CD-ROM, Diskette, Internet Entry, etc.

FDA believes that the burden imposed by this rule is minimal and no reduction in burden is necessary or possible.

**4. Efforts to Identify Duplication and Use of Similar Information**

Only State and local governments have the necessary information to apply for exemption from preemption. There is, therefore, no duplication.

**5. Impact on Small Businesses or Other Small Entities**

Only State and local governments are the appropriate parties to apply for exemption from preemption. This regulation will have no effect on small businesses.

**6. Consequences of Collecting the Information Less Frequently**

Under the act, a State and local government may not enforce a preempted requirement unless the government applies for and receives an exemption from preemption.

**7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

These information collections are consistent with the requirements of 5 CFR 1320.5.

**8. Efforts to Consult Outside Agency**

In accordance with 5 CFR 1320.8(d) on Tuesday, January 18, 2000, a 60 day notice for public comment (Attachment D) was published in the Federal Register. No comments were received.

**9. Explanation of Any Payment or Gift to Respondents**

There will be no payments or gifts to respondents for this information collection.

**10. Assurance of Confidentiality Provided to Respondent**

FDA does not expect any confidential information to be submitted in these information collections. Any information submitted in these applications will be kept confidential, when required by the implementing regulations for the Freedom of Information Act 95 U.S.C. 552) found in 21 CFR Part 20.

**11. Justification for Sensitive Questions**

This information collection does not include questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

**12. Estimates of Hour Burden Including Annualized Hourly Costs**

**21 CFR 808.20 - Applications**

The number of applications may vary quite a bit from year to year. Based on its experience to date, FDA expects, on the average, no more than 3 applications per year. Based on its discussions with States that have submitted applications, FDA estimates that it will take approximately 100 hours for preparation of an application. At a cost of \$25 per hour for a State or local government employee, the total cost of preparing an application is \$2,500. At 3 applications per year, the total annual cost would be \$7,500 per year.

**21 CFR 808.25(d) - Request for Hearing**

If each applicant requested a hearing, there would be 3 requests per year, on the average, for a hearing. The hearing request is a simple letter. Including the time for discussing whether requesting a hearing is appropriate, FDA estimates that it will take 10 hours to submit such a request. At 3 requests per year, this would result in an annual burden of 30 hours. At \$25 per hour, the annual cost would be \$ 750 per year.

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

Table 1. -- Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
808.20	3	1	3	100	300
808.25	3	1	3	10	30
Subtotal Regulatory					330
TOTAL					330

There are no capital costs or operating and maintenance costs associated with this collection of information

FDA based its estimates of future submissions in the above table on the number of submissions submitted in the last 3 years and the number of inquiries received (indicating the number of applications that would be submitted in the next year.) FDA based its estimates of the time required to prepare submissions on discussions with respondents who have prepared submissions in the last 3 years. Persons are not required to respond to a collection of information unless it displays a valid control number.

There are no recordkeeping requirements in this rule.

**13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers**

There are no capital or operating/maintenance costs associated with this regulation.

**14. Annualized Cost to the Federal Government**

FDA is currently spending approximately .25 FTEs per year to implement this information collection. Based on experience, FDA estimates that it will continue to expend .25 FTEs to

review 3 applications per year. At an average annual cost per FTES (including overhead) of \$89,705, the total annual cost to the Federal government will be approximately \$ 22,425.

**15. Explanation for Program Changes or Adjustments**

There is no change in the burden hours from the existing approved information collection.

**16. Plans for Tabulation and Publication and Project Time Schedule**

FDA does not intend to publish the results of this information collection.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

FDA is not seeking an exemption from the requirement to display the effective date.

**18. Exception to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification statement in item 19 of OMB Form 83-I.

**B. Collection of Information Employing Statistical Methods**

There are no statistical methods being employed in this collection of information.

**List of Attachments to Supporting Statement:**

Tab A - 21 CFR Part 808

Tab B - Section 521 of the F,D & C Act

Tab C - Final rule on Electronic Reporting

Tab D - 60 Day Federal Register Notice