

United States Food & Drug Administration

Human Drug Compounding, Repackaging, and Related Activities
Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control No. 0910-0858 -- EXTENSION

SUPPORTING STATEMENT

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

This information collection helps support implementation of sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a and 21 U.S.C. 353b), which govern compounding by pharmacies, outsourcing facilities, and other entities. Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Although compounded drugs can serve an important medical need for certain patients, they also present risks to patients. The Food and Drug Administration's (FDA or the Agency) compounding program aims to protect patients from unsafe, ineffective, and poor-quality compounded drugs while preserving access to lawfully marketed compounded drugs for patients who have a medical need for them. The information collection also supports FDA policies that provide conditions for the continuation of certain drug production activities by pharmacy compounders and outsourcing facilities that are not provided for under sections 503A or 503B of the FD&C Act.

To assist respondents in complying with statutory requirements, we have issued topic-specific guidance documents:

Table 1.--Published Guidance Documents Regarding Sections 503A and 503B of the FD&C Act

Title	Notice of Availability; Publication Date
Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities (Radiopharmaceutical Compounding and Repackaging Guidance) (available at https://www.fda.gov/media/102615/download)	September 26, 2018 (83 FR 48633)
Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities (Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance) (available at https://www.fda.gov/media/102637/download)	September 26, 2018 (83 FR 48630)
Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities (Repackaging Guidance) (available at https://www.fda.gov/media/90978/download)	January 13, 2017 (82 FR 4343)
Mixing, Diluting, or Repackaging Biological Products Outside the Scope	January 19, 2018

of an Approved Biologics License Application (Biological Products Guidance) (available at https://www.fda.gov/media/90986/download)	(83 FR 2787)
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These guidance documents were issued consistent with FDA’s good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time. The guidance documents communicate FDA’s current thinking on the respective topics and include information collection that may result in expenditures of time and effort by respondents. In FDA’s notices of availability for the guidance documents, we also solicited public comment under the PRA on the information collection provisions. FDA has developed and maintains a searchable guidance database available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Guidance documents covered by this information collection may be found by choosing “Center for Drug Evaluation and Research” from among the FDA Organizations, and by selecting the term “Compounding” from among the possible filters.¹

The guidance documents also describe conditions under which FDA generally does not intend to take enforcement action for violations of certain sections of the FD&C Act. We believe any information collection pertaining to enforcement activities would involve administrative actions to which the Federal government is a party or that occur after an administrative case file has been opened regarding a particular individual or entity and would be exempt from Office of Management and Budget (OMB) review and approval under the Paperwork Reduction Act of 1995 (PRA). See 44 U.S.C. 3518(c)(1)(B); and 5 CFR 1320.4(a)(2) and (c).

We therefore request OMB approval of the information collection recommendations found in the respective guidance documents and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The information collection associated with the conditions discussed in the respective guidance documents are tailored to address serious concerns that have been raised and to protect patients from unsafe products. We intend for the information collection recommendations to assist respondents in complying with statutory and regulatory requirements administered by FDA to promote and protect the public health.

Respondents to the information collection are pharmacy compounders, outsourcing facilities and other entities.

3. Use of Improved Information Technology and Burden Reduction

Outsourcing facilities submit their initial and biannual product reports identifying drug products repackaged during the previous 6-month period to FDA via the Agency’s electronic Drug Registration and Listing System (eDRLS) as explained in the Radiopharmaceutical Compounding and Repackaging Guidance by Outsourcing Facilities and the Repackaging Guidance.

¹Guidance documents applicable to animal drug compounding regulated by the Center for Veterinary Medicine would also be returned if no FDA Organization is selected; this information collection covers only those compounding guidance documents issued by the Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research.

Because electronic reporting and recordkeeping requirements are found in both applicable and related Agency statutes and regulations, we expect all respondents will utilize electronic means to satisfy the information collection. If electronic submission is unreasonable for a particular outsourcing facility, the outsourcing facility may request a waiver from FDA to submit the report through an alternative means. We continue to seek ways to increase the utility of Agency operating systems as our resources permit.

We expect nearly 100 percent of respondents to report electronically for initial product reports and semiannual reports. We expect to receive very few waiver requests from the electronic submission process for any reports.

4. Efforts to Identify Duplication and Use of Similar Information

Upon review of our active inventory, we have identified other information collection requests associated with, but not duplicative of, provisions of the FD&C Act including OMB control nos. 0910-0776 – *Registration of Human Drug Compounding Outsourcing Facilities under section 503B of the FDCA and Associated fees under section 744K*; and 0910-0800 – *Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act*. We note also related reporting, recordkeeping, and disclosure requirements applicable under the Controlled Substances Act, for which currently active information collection approvals are maintained by the Department of Justice’s Drug Enforcement Administration. For efficiency of Agency operations, we will continue to evaluate related information collections and incorporate similar activities as appropriate.

5. Impact on Small Businesses or Other Small Entities

Radiopharmaceuticals, repackaged drug products, and biological products that have been altered outside the scope of the approved biologics license application present unique and significant public health risks. Although most State-licensed nuclear pharmacies, State-licensed pharmacies, and outsourcing facilities are small businesses as defined by the Small Business Administration, we do not believe the information collection imposes undue burden on small entities. At the same time, we assist small businesses in complying with FDA regulations through Regional Small Business Representatives and through scientific and administrative staffs within the Agency. We have also provided a Small Business Guide on our website at <http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm>.

6. Consequences of Collecting the Information Less Frequently

The information collection schedules recommended in the respective guidance documents are consistent with applicable statutes and regulations. Collecting the information less frequently could undermine our ability to monitor unapproved drug products.

7. Special Circumstances Relating to the Guidelines in 5 CFR § 1320.5

No special circumstances are associated with this information collection.

8. Comments in Response to the *Federal Register* Notice and Efforts to Consult Outside the Agency

In the Federal Register of 06/12/24 (89 FR 49880), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Data will be kept private to the extent provided by law.

The Privacy Act of 1974

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted via the CDER Direct Electronic Submissions Portal is name, address, telephone number, and email address of drug product report submitter. We have determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Hour Burden and Costs

12a. Annualized Hour Burden Estimate

Table 2.-- Estimated Annual Reporting Burden¹

Recommended Activity; Guidance Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
RADIOPHARMACEUTICAL COMPOUNDING AND REPACKAGING BY OUTSOURCING FACILITIES GUIDANCE					
Biannual product reports identifying drug products repackaged by the outsourcing facility during the previous 6-month period (section III.B of the Radiopharmaceutical Compounding and Repackaging Guidance by Outsourcing Facilities)	2	2	4	3	12
REPACKAGING GUIDANCE²					
Biannual product reports identifying drug products repackaged by the outsourcing facility during the previous 6-month period (section III.A of the Repackaging Guidance)	6	2	12	3	36
Total	8		16		48

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

²We estimate a total of 6 unique respondents will submit biannual product reports for the Repackaging Guidance and that those same 6 respondents will also design, test, and produce labels as a third-party disclosure. To avoid double-counting, these respondents are only counted once although are listed in both the reporting and third-party disclosure tables.

Table 3.--Estimated Annual Recordkeeping Burden¹

Recommended Activity; Guidance Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
RADIOPHARMACEUTICAL COMPOUNDING AND REPACKAGING GUIDANCE					
Consultation between the compounder and prescriber and the notation on the prescription or order documenting the prescriber's determination of clinical difference (section III.A of the Radiopharmaceutical Compounding and Repackaging Guidance)	10	25	250	.05 (3 minutes)	12.5
BIOLOGICAL PRODUCTS GUIDANCE					
Maintaining records of testing performed in accordance with Appendix A in the Biological Products Guidance (section III.B of the Biological Products Guidance)	5	30	150	0.083 (5 minutes)	12.5
Total	15		400		25

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

Table 4. – Estimated Annual Third-Party Disclosure^{1,2}

Recommended Activity; Guidance Section	No. of Respondents ²	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
RADIOPHARMACEUTICAL COMPOUNDING AND REPACKAGING BY OUTSOURCING FACILITIES GUIDANCE					
Designing, testing, and producing each label on immediate containers, packages and/or outer containers (section III.B of the Radiopharmaceutical Compounding and Repackaging Guidance by Outsourcing Facilities)	2	5	10	0.5 (30 minutes)	5
REPACKAGING GUIDANCE					
Designing, testing, and producing each label on immediate containers, packages, and/or outer containers (section III.A of the Repackaging Guidance)	6	36	216	1	216
BIOLOGICAL PRODUCTS GUIDANCE					
Designing, testing, and producing the label, container, packages, and/or outer containers for each mixed, diluted, or repackaged biological product (section III.B of the Biological Products Guidance)	15	5	75	0.5 (30 minutes)	37.5
Designing, testing, and producing each label on immediate containers, packages and/or outer containers for each licensed allergenic extract (section III.C of the Biological Products Guidance)	5	300	1,500	0.5 (30 minutes)	750
Total	28		1,801		1,009

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

²Totals may not sum due to rounding.

The total burden for this information collection is 1,082 hours.

For purposes of our analysis, we characterize the burden associated with the time and effort expended on the information collection recommendations discussed in the respective guidance documents as either recordkeeping, reporting or third-party disclosure activities. We reconfigured the original table by splitting it into three tables to better differentiate between the estimated annual recordkeeping burden, the estimated annual reporting burden, and the estimated annual third-party disclosure burden. At the same time, our findings show that compliance with recordkeeping requirements applicable to compounded and repackaged drug products is standard practice in the compounding and selling of these drug products under States' pharmacy laws and other State laws governing recordkeeping by healthcare professionals and healthcare facilities. Therefore, we excluded from our estimate recordkeeping practices discussed in the respective guidance documents we consider usual and customary.

Our estimated burden for the information collection reflects constant respondent numbers (33 unique respondents). The original numbers were based on the information the program received from product reporting data. We do not have a mechanism in place to determine whether or not these numbers have fluctuated upward or downward; however, based on analogous observations of industry through program experience (some product reports), we believe these numbers are constant. Repackagers who are also registered as outsourcing facilities (OF) are not entity types that are individually regulated as repackagers. They are subsumed in the OF entity type and not easily distinguishable. They may or may not report their repackaging operations.

Radiopharmaceutical Compounding and Repackaging Guidance

Because Congress explicitly excluded radiopharmaceuticals from section 503A of the FD&C Act (see section 503A(d)(2)), compounded radiopharmaceuticals are not eligible for the exemptions under section 503A from section 505 of the FD&C Act (21 U.S.C. 355) (concerning new drug approval requirements), section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) (concerning labeling with adequate directions for use), and section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP) requirements). In addition, the FD&C Act does not provide an exemption for repackaged radiopharmaceuticals. The guidance describes the conditions under which FDA does not intend to take action for violations of sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act when a State-licensed nuclear pharmacy, Federal facility, or other facility that is not an outsourcing facility and that holds a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State compounds or repackages radiopharmaceuticals for human use.

The guidance explains that one condition is that the compounded radiopharmaceutical is not essentially a copy of an approved radiopharmaceutical. As described in the guidance, FDA

does not intend to consider a compounded radiopharmaceutical to be essentially a copy if, among other reasons, there is a change between the compounded radiopharmaceutical and the approved radiopharmaceutical that produces a clinical difference for an identified individual patient, as determined by the prescribing practitioner and documented in writing on the prescription or order. In addition, FDA does not intend to consider a compounded radiopharmaceutical to be essentially a copy if the FDA-approved radiopharmaceutical is on FDA's drug shortage list (see section 506E of the FD&C Act (21 U.S.C. 356e)) at the time of compounding and distribution. If the facility compounded a drug that is identical or nearly identical to an approved drug product that appeared on FDA's drug shortage list, the facility should maintain documentation (e.g., a notation on the order for the compounded drug) regarding the status of the drug on FDA's drug shortage list at the time of compounding, distribution, and dispensing.

We estimate 10 compounders annually will consult a prescriber to determine whether a compounded radiopharmaceutical has a change that produces a clinical difference for an identified individual patient as compared to the comparable approved radiopharmaceutical. We estimate that those compounders will document this determination on 250 prescriptions or orders for compounded radiopharmaceuticals. We assume consultation between the compounder and the prescriber and noting this determination on each prescription or order that does not already document this determination will take 3 minutes (0.05 hours) per prescription or order, for a total of approximately 12.5 hours.

Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance.

In contrast to section 503A, section 503B of the FD&C Act does not exclude radiopharmaceuticals. Therefore, FDA's overall policies regarding section 503B of the FD&C Act apply to the compounding of radiopharmaceuticals. However, we have developed specific policies that apply only to the compounding of radiopharmaceuticals by outsourcing facilities using bulk drug substances and to the compounding of radiopharmaceuticals by outsourcing facilities that are essentially copies of approved drugs when such compounding is limited to minor deviations, as that term is defined in the guidance. FDA issued this guidance in part to describe the conditions under which the Agency does not generally intend to take action for violations of sections 505 and 502(f)(1) of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals for human use. As discussed in the guidance, one condition is that if a radiopharmaceutical is repackaged by an outsourcing facility, the label on the immediate container (primary packaging, e.g., the syringe) of the repackaged product includes certain information described in the guidance.

We estimate a total of 2 outsourcing facilities annually will each design, test, and produce an average of 5 different labels for a total of 10 labels, as described in the guidance (including directions for use). We assume that designing, testing, and producing each label will take 30 minutes (0.5 hours) for each repackaged radiopharmaceutical, for a total of 5 hours.

Both the Radiopharmaceutical Compounding and the Repackaging by Outsourcing Facilities Guidance documents provide that the labeling on the container from which the individual units are removed for administration should include certain information described in the

guidance: (1) the active and inactive ingredients, if the immediate product label is too small to include this information, and directions for use, including (as appropriate) dosage and administration and (2) the following information to facilitate adverse event reporting: <https://www.fda.gov/medwatch and 1-800-FDA-1088>.

For the Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance, a row for biannual product reporting was added to capture product reporting that was inadvertently omitted.

Repackaging Guidance

The guidance describes the conditions under which FDA does not intend to take action for violations of sections 505 (concerning new drug applications), 502(f)(1) (concerning labeling with adequate directions for use), 582 ((21 U.S.C. 360eee-1) concerning drug supply chain security requirements), and (where specified in the guidance) 501(a)(2)(B) of the FD&C Act (concerning CGMPs), when a State-licensed pharmacy, Federal facility, or outsourcing facility repackages certain prescription drugs. One condition discussed in the guidance is that if a drug is repackaged by an outsourcing facility, the label on the immediate container (primary packaging, e.g., the syringe) of the repackaged product includes certain information described in the guidance.

Conditions discussed in the guidance include that if a drug is repackaged by an outsourcing facility, the label on the immediate container (primary packaging, e.g., the syringe) and on the container from which the individual units are removed for administration (secondary packaging, e.g., the bag, box, or other package in which the repackaged products are distributed) of the repackaged product include certain information described in the guidance.

Based on current data for outsourcing facilities, we estimate six outsourcing facilities annually will submit an initial report identifying all drugs repackaged in the facility in the previous year. For the purposes of this estimate, each product's structured product labeling (SPL) submission is considered a separate response, and therefore each facility's product report will include multiple responses. Taking into account that a particular product that is repackaged may come in different strengths and can be reported in a single SPL response, we estimate that each facility will average approximately thirty-six products.

Similarly, we estimate that six outsourcing facilities will submit an initial report identifying all drugs repackaged in the facility in the past year. Taking into account that a particular product that is repackaged may come in different strengths and can be reported in a single SPL response, we assume that each facility will average thirty-six products. Our estimate is based on current product reporting data. We expect that each product report will consist of multiple SPL responses per facility and assume preparing and electronically submitting this information will take up to 3 hours for each initial SPL response.

We also estimate two registered outsourcing facilities will submit a report twice each year (June and December) that identifies all drugs repackaged at the facility in the previous 6 months. We also estimate that an average of two facilities will prepare and submit two SPL

responses and assume that preparing and submitting this information electronically will take 3 hours per response. If a product was not repackaged during a particular reporting period, outsourcing facilities do not need to send an SPL response for that product during that reporting period. We expect to receive no waiver requests from the electronic submission process for initial product reports and semiannual reports. (Reporting by registered outsourcing facilities is currently approved under OMB control no. 0910-0776).

For the Repackaging Guidance, to correct a clerical error, we have adjusted the number of disclosures per respondent from 21 to 36 because each respondent is estimated to average 6 different products and average 6 different strengths, which requires 36 (6 x 6) unique labels per respondent. The initial narrative reflected that each product would come in 6 different strengths and thus require 6 unique labels, but due to a clerical error, this information was not correctly included in the table. We also adjusted the number of respondents to 6 to match the number of respondents designing, testing, and producing labels. In addition, we adjusted the total number of disclosures per respondent to 2 given the biannual reporting requirement.

Biological Products Guidance

Certain licensed biological products may sometimes be mixed, diluted, or repackaged in a way not described in the approved labeling for the product to meet the needs of a specific patient. As described in the guidance, biological products subject to licensure under section 351 of the Public Health Service (PHS) Act (42 U.S.C. 262) are not eligible for the statutory exemptions available to certain compounded drugs under sections 503A and 503B of the FD&C Act. In addition, a biological product that is mixed, diluted, or repackaged outside the scope of an approved biologics license application (BLA) is considered an unlicensed biological product under section 351 of the PHS Act.

This guidance document describes several conditions under which FDA does not intend to take action for violations of section 351 of the PHS Act and sections 502(f)(1), 582, and (where specified) 501(a)(2)(B) of the FD&C Act, when a State-licensed pharmacy, a Federal facility, or an outsourcing facility dilutes, mixes, or repackages certain biological products outside the scope of an approved BLA.

One condition discussed in the guidance is that if the labeling for the licensed biological product includes storage instructions, handling instructions, or both (e.g., protect from light, do not freeze, keep at specified storage temperature), the labeling for the biological product that is mixed, diluted, or repackaged specifies the same storage conditions. Another condition described in the guidance is that, if the biological product is mixed, diluted, or repackaged by an outsourcing facility, the label on the immediate container (primary packaging, e.g., the syringe) of the mixed, diluted, or repackaged product includes certain information described in the guidance. In addition, the guidance communicates that as a condition for biological products mixed, diluted, or repackaged by an outsourcing facility that, if the immediate product label is too small to bear the active and inactive ingredients, such information is included on the label of the container from which the individual units are removed for administration (secondary packaging, e.g., the bag, box, or other package in which the mixed, diluted, or repackaged biological products are distributed).

The guidance also communicates FDA’s thinking about the condition for biological products mixed, diluted, or repackaged by an outsourcing facility that the label on the container from which the individual units are removed for administration include directions for use. These directions include, as appropriate, the dosage and administration and the following information to facilitate adverse event reporting: <https://www.fda.gov/medwatch> and 1-800-FDA-1088.

Finally, another condition described in the guidance is that outsourcing facilities maintain records of the testing performed in accordance with “Appendix A--Assigning a BUD for Repackaged Biological Products Based on Stability Testing” of the guidance for biological products repackaged by outsourcing facilities for which the beyond use date (BUD) is established based on a stability program conducted in accordance with Appendix A. Section III.C of the guidance, “Licensed Allergenic Extracts for Subcutaneous Immunotherapy,” discusses the preparation of prescription sets (i.e., licensed allergenic extracts that are mixed and diluted to provide subcutaneous immunotherapy to an individual patient) by a physician, a State-licensed pharmacy, a Federal facility, or an outsourcing facility. Another condition described in the guidance is that if the prescription set is prepared by an outsourcing facility, the label of the container from which the individual units of the prescription set are removed for administration (secondary packaging) includes the following information to facilitate adverse event reporting: <https://www.fda.gov/medwatch> and 1-800-FDA-1088. Each prescription set prepared by an outsourcing facility is also accompanied by instructions for use.

We estimate 15 outsourcing facilities annually that mix, dilute, or repackage biological products will each design, test, and produce 5 different labels, for a total of 75 labels that include the information set forth in section III.B, “Mixing, Diluting, or Repackaging Licensed Biological Products,” of the Biological Products Guidance (including directions for use) as well as inclusion of storage instructions, handling instructions, or both. We assume that designing, testing, and producing each label will take 30 minutes (0.5 hours).

We estimate that annually a total of 5 outsourcing facilities who prepare prescription sets will each include on the labels, packages, and/or containers of approximately 300 prescription sets the information set forth in section III.C, “Licensed Allergenic Extracts for Subcutaneous Immunotherapy,” of the Biological Products Guidance (including directions for use), for a total of 1,500 disclosures. We assume the initial process of designing, testing, and producing labeling and attaching to each prescription set each label, package, and/or container will take approximately 30 minutes (0.5 hours), for a total of approximately 750 hours.

Finally, we estimate that annually five outsourcing facilities that repackage biological products and establish a beyond use date (BUD) in accordance with “Appendix A – Assigning a BUD for Repackaged Biological Products Based on Stability Testing” will maintain 150 records of the testing, as described in Appendix A of the Biological Products Guidance. We assume maintaining the records will take 5 minutes per record, for a total of 12.5 hours.

12b. Annualized Cost Burden Estimate

Radiopharmaceutical Compounding and Repackaging Guidance

The industry burden estimate calculated above would result in labor costs. For the Radiopharmaceutical Compounding and Repackaging Guidance, we estimate that the notations on a prescription described above are generally captured by and records are maintained by a pharmacist and that labor hours are valued using the mean hourly wage of \$64.81 as reported by the U.S. Department of Labor, Bureau of Labor Statistics (DOL BLS). Wages are further adjusted for benefits and overhead, for an average hourly labor cost of \$79.22 (\$64.81 + \$14.41). Using this wage rate multiplied by 12.5 hours for recordkeeping calculated above collection equals approximately \$990 ($\79.22×12.5) in labor costs.

Radiopharmaceutical Compounding and Repackaging by Outsourcing Guidance

For the Radiopharmaceutical Compounding and Repackaging Outsourcing Facilities Guidance labeling recommendations, we estimate that designing the labels would be performed by a pharmacist and a graphic designer. Labor hours are valued using the mean hourly wage of \$64.81 (pharmacist) and \$31.11 (graphic designer) as reported by the U.S. DOL BLS. Wages are further adjusted for benefits and overhead, for an average hourly labor cost of \$79.22 (\$64.81 + \$14.41) and \$45.25 (\$31.11 + \$14.14). Using these wage rates multiplied by 5 hours for the annual third-party disclosure burden split equally between a graphic designer and a pharmacist (\$62.24) equals approximately \$311. Using these wage rates multiplied by 12 hours for the biannual product reporting by the pharmacist equals approximately \$951. The total cost associated with this guidance is \$1,262 ($\$311 + \951).

Repackaging Guidance

For the Repackaging Guidance product reporting and labeling recommendations, we estimate that designing the labels would be performed by a pharmacist and a graphic designer and the reporting would be performed by a pharmacist. Labor hours are valued using the mean hourly wage of \$64.81 (pharmacist) and \$31.11 (graphic designer) as reported by the U.S. DOL BLS. Wages are further adjusted for benefits and overhead, for an average hourly labor cost of \$79.22 (\$64.81 + \$14.41) and \$45.25 (\$31.11 + \$14.14). Using these wage rates multiplied by 216 hours split between a pharmacist (25%) and a graphic designer (75%), calculated above for the annual third-party disclosure burden, equals approximately \$7,331 ($\45.25×162) + \$4,278 ($\79.22×54). Using these wage rates multiplied by 36 hours for the biannual product reporting by the pharmacist equals approximately \$2,852 ($\79.22×36). The total cost associated with this guidance is \$14,461 ($\$11,609 + \$2,852$).

Biological Products Guidance

For the Biological Products Guidance product reporting and labeling recommendations, we estimate that designing the labels would be performed by a pharmacist and a graphic designer, and reporting would be performed by a pharmacist. Labor hours are valued using the mean hourly wage of \$64.81 (pharmacist) and \$31.11 (graphic designer) as reported by the U.S.

DOL BLS. Wages are further adjusted for benefits and overhead, for an average hourly labor cost of \$79.22 (\$64.81 + \$14.41) and \$45.25 (\$31.11 + \$14.14). Using these wage rates multiplied by 788 hours split between a pharmacist (25%) and a graphic designer (75%) calculated above for the annual third-party disclosure burden equals approximately \$42,439 [\$15,606 (\$79.22 x 197) + \$26,743 (\$45.25 x 591)]. Using these wage rates multiplied by 12.5 hours for the recordkeeping by the pharmacist equals approximately \$990 (\$79.22 x 12.5). We estimate the total annual cost associated with this guidance for annual third-party disclosure and recordkeeping to be approximately \$42,349 (\$66,987 + \$990).

13. Estimates of Other Total Annual Cost Burden to Respondents and/or Recordkeepers/Capital Costs

We assume there are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We have allocated 0.2 full-time equivalent (\$27,500) (GS-13, Step 6) to review and evaluate prescription records maintained by compounders that are annotated to include prescriber determinations and to review labels or reports regarding repackaged drug products.

15. Explanation for Program Changes or Adjustments

We are updating the information collection to include burden attendant to reporting and disclosure recommendations found in the Agency guidance documents that was inadvertently omitted in the original information collection due to clerical errors. The burden estimate is adjusted to reflect a resulting increase of 114 hours and 94 responses annually.

16. Plans for Tabulation and Publication and Project Time Schedule

No tabulation or publication of the information collection is planned.

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

We will display the OMB expiration data as required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.