

## **Supporting Statement for Renewal of Existing Information Collection Request for Confidentiality Rules**

### **1. Identification of the Information Collection**

#### **1(a) Renewal of Existing Information Collection Request for Confidentiality Rules; EPA ICR No. 1665.10, OMB Control No 2020-0003.**

#### **1(b) Short Characterization**

The U.S. Environmental Protection Agency (EPA) originally established the procedures described in 40 CFR, Part 2, subpart B, in 1976 to protect the confidentiality of information while also respecting the rights of the public to obtain access to information under the Freedom of Information Act (FOIA, 5 U.S.C. §552).

This request for the renewal of an existing information collection request (ICR) covers the existing provisions in 40 CFR, Part 2, subpart B. These provisions describe:

- ◆ the procedures industry must follow in asserting and justifying confidentiality claims;
- ◆ the procedures EPA must follow in reviewing business information claimed as confidential, notifying and providing affected businesses with an opportunity to comment, reviewing industry substantiations, and making final confidentiality determinations; and
- ◆ the requirement for the signing and maintenance of confidentiality agreements by all contractor/subcontractor employees who are given access to confidential information in the course of performing work for EPA.

#### **OMB Terms of Clearance**

In the previous ICR renewal OMB had these terms of clearance, "Prior to resubmission of this request for extension, the Agency should reassess burden taking into account recent experience of respondents and changes in EPA's reporting programs. In addition, the Agency should describe its method for estimating burden." The Agency's response is that as part of the ICR review EPA contacted organizations that actually respond to substantiation requests as set forth in item 3(c) of the Supporting Statement. The burden estimates are predicated upon input from the organizations and input from EPA staff.

### **2. Need For and Use of the Collection**

#### **2(a) Need/Authority for the Collection**

EPA administers a number of environmental protection statutes, (e.g., the Clean Water Act; the Clean Air Act; the Toxic Substances Control Act; the Federal Insecticide,

Fungicide and Rodenticide Act; the Resource Conservation and Recovery Act; and the Comprehensive Environmental Response, Compensation, and Liability Act) under which the Agency collects information, such as data on toxic chemicals, waste streams, industrial processes, and regulatory compliance, from facilities in many economic sectors. In addition, businesses submit information to EPA without the Agency requesting it. In many instances, companies consider the information they submit to EPA to be confidential business information (CBI).

In accordance with 40 CFR Part 2, subpart B, when EPA finds it necessary to make a final confidentiality determination (e.g., in response to a FOIA request or in the course of rulemaking or litigation), or an advance confidentiality determination, it notifies the affected business by sending a letter requesting substantiation of the confidentiality claim. This letter provides the affected business with an opportunity to submit comments (i.e., substantiation). Industry comments are very helpful to EPA in making final confidentiality determinations.

When EPA utilizes contractor/subcontractor services for activities involving CBI, the contractor/subcontractor must ensure that all its employees who will be given access to CBI have signed confidentiality agreements. These agreements state that employees shall use the confidential information only for the work in the contract/subcontract, shall refrain from disclosing the information, and shall return all copies of the information to EPA upon request or completion of the project. The contractor/subcontractor company must also maintain a file of these confidentiality agreements.

The procedures laid out in 40 CFR, Part 2, subpart B, derive their authority from FOIA, as amended, 5 U.S.C. 552, the Trade Secrets Act, as amended, 18 U.S.C. 1905, the Federal housekeeping statute, as amended, 5 U.S.C. 301, the Administrative Procedure Act, as amended, 5 U.S.C. 551, et seq., and the confidentiality provisions of environmental statutes administered by EPA, as follows:

- §114, 206, 208, 301, and 307, Clean Air Act, as amended (42 U.S.C. 7414, 7525, 7542, 7601, 7607)
- §§308, 501, and 509(a), Clean Water Act, as amended (33 U.S.C. 1318, 1361, 1369(a))
- §13, Noise Control Act of 1972, as amended (42 U.S.C. 4912)
- §§1445 and 1450, Safe Drinking Water Act, as amended (42 U.S.C. 300j-4, 300j-9)
- §§2002, 3001, 3007, and 9005, Resource Conservation and Recovery Act, as amended (42 U.S.C. 6912, 6921, 6927, 6991d)
- §§8(c), 11, 12(b), and 14, Toxic Substances Control Act, as amended (15 U.S.C. 2607(c), 2610, 2611(b), 2613)
- §§10, 12, and 25, Federal Insecticide, Fungicide, and Rodenticide Act, as amended, (7 U.S.C. 136h, 136j, 136w)
- §408(i), Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 346a(i))

- §§104(f) and 108, Marine Protection Research and Sanctuaries Act of 1972, as amended (33 U.S.C. 1414(f), 1418)
- §§104 and 115, Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (42 U.S.C. 9604, 9615)

## 2(b) **Use/Users of the Data**

EPA will use the information received from industry to help determine whether particular information has been claimed as confidential, whether the Agency needs to make a formal confidentiality determination, and whether the information in question is indeed entitled to confidential treatment under Exemption 4 of FOIA.

## 3. **Non-Duplication, Consultations and Other Collection Criteria**

### 3(a) **Non-Duplication**

This information is not elsewhere collected from businesses.

### 3(b) **Public Notice Required Prior to ICR Submission to OMB**

EPA published a notice of the renewal of the existing information collection request for confidentiality rules in the *Federal Register* on September 28, 2010 (75 FR 59708) and invited public comments.

### 3(c) **Consultations**

As part of its efforts for renewing its ICR, EPA sought to evaluate whether the burden to small businesses associated with preparing substantiations fell within the burden range established in the Renewal ICR. Using information provided by multiple EPA offices, the Agency confirmed that the burden range was updated according to the information provided.

EPA contacted the following organizations:

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Cynthia Taub  
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(202) 429-8133

Lawrence A. Miller  
Biologic, Inc.  
115 Obtuse Hill  
Brookfield, Connecticut 06804  
(203) 740-1200

### **3(d) Effects of Less Frequent Collection**

Not applicable.

### **3(e) General Guidelines**

Only one provision of this collection exceeds the Paperwork Reduction Act guidelines at 5 CFR 1320.5(d)(2). This collection calls for responses to be furnished to EPA within 15 working days after the business receives the letter requesting substantiation. Under 5 CFR 1320.5(d)(2)(ii), EPA must justify why the response needs to be prepared within a period shorter than 30 days after receipt of the collection. In the context of addressing the time-frame for determinations under the FOIA, EPA “tentatively” determined that 15 days is “a reasonable period for the business to furnish comments and substantiating data concerning its claim.” 40 FR 21987, 21988, 21989 (May 20, 1975) and 41 FR 36902, 36908 (September 1, 1976). EPA has found through experience in the years since these regulations were promulgated (at 40 CFR Part 2) that 15 days fits well with the general timetable of FOIA responses.

### **3(f) Confidentiality and Sensitive Questions**

#### **1. Confidentiality**

Under EPA’s current CBI regulations (40 CFR Part 2, subpart B), respondents may claim substantiations submitted to EPA as confidential.

#### **2. Sensitive Questions**

Not applicable. This information collection does not include questions of a sensitive nature.

## **4. The Respondents and the Information Requested**

### **4(a) Respondents/SIC Codes**

Respondents could potentially include any business submitting a document to EPA that it claims as CBI. EPA receives such information from both the manufacturing (SIC codes 20-39) and non-manufacturing sectors (no SIC codes identified).

#### 4(b) **Information Requested**

##### A. *Substantiation of confidentiality claim*

Whenever EPA finds it necessary to determine the confidentiality of information that has been claimed as CBI (e.g., in response to a FOIA request or in connection with rulemaking or litigation, or with regard to an advance confidentiality determination) (40 CFR 2.204 (a), (c) and (d), 2.206), it must notify affected businesses orally and in writing and provide them with an opportunity to comment (40 CFR 2.204(e)).

With this Renewal ICR, EPA is proposing to use the attached Request for Substantiation letters. The proposed six proposed address different factual situations which require EPA to determine the confidentiality of information claimed CBI: Letters A and E; requests a generic substantiation; Letter B; requests an inert ingredient substantiation; Letter C; request a complex substantiation; Letter D; requests a complex substantiation questions for health and safety filings containing information claimed as confidential; and Letter F; requests information used in an advance or final confidentiality determination.

##### 1. Data Items

The written notice from EPA (40 CFR 2.204(e)(1) and (4)) invites the business's comments on the following:

- (i) The portions of the information which are alleged to be entitled to confidential treatment;
- (ii) The period of time for which confidential treatment is desired by the business (e.g., until a certain date, until the occurrence of a specified event, or permanently);
- (iii) The purpose for which the information was furnished to EPA and the approximate date of submission, if known;
- (iv) Whether a business confidentiality claim accompanied the information when it was received by EPA;
- (v) Measures taken by the business to guard against undesired disclosure of the information to others;
- (vi) The extent to which the information has been disclosed to others, and the precautions taken in connection therewith;
- (vii) Pertinent confidentiality determinations, if any, by EPA or other Federal agencies; and a copy of any such determination, or reference to it, if available;

- (viii) Whether the business asserts that disclosure of the information would be likely to result in substantial harmful effects on the business's competitive position, and if so, what those harmful effects would be, why they should be viewed as substantial, and an explanation of the causal relationship between disclosure and such harmful effects; and
- (ix) Whether the business asserts that the information is voluntarily submitted information as defined in 40 CFR §2.201(i), and if so, whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.

2. Respondent Activities

To complete the collection, the respondent must:

- a. Read EPA's request for comments;
- b. Review the information claimed as confidential; and
- c. Prepare and submit substantiation to EPA.

*B. Designation by Business of Addressee for Notices and Inquiries*

Pursuant to 40 CFR 2.213, a business may elect to designate an official contact for inquiries and notices concerning confidentiality claims.

1. Data Items

Name and address of the business making the designation, and the name and address of the designated person or office.

2. Respondent Activities

To identify and submit the information to EPA.

*C. Confidentiality agreements*

When EPA utilizes the services of contractors/subcontractors, all contractor/subcontractor employees who may be given access to confidential information must first sign confidentiality agreements stating that they will honor the terms of the contract/subcontract which requires protection of CBI. See, e.g., 40 CFR 2.301(h)(2)(ii).

1. Data Items

Signed confidentiality agreements.

2. Respondent activities

The contractor must:

- a. Require each employee given access to CBI to read and sign a confidentiality agreement, and
- b. Maintain a file of such agreements. See 40 CFR 2.301(h)(2)(iv).

In addition to the information collections discussed above, when EPA intends to disclose CBI to contractors/subcontractors, other Federal agencies, or Congress, EPA generally notifies affected businesses. During a specified period of time prior to disclosure, businesses may submit comments. Industry has rarely submitted comments to EPA under these circumstances.

## **5. The Information Collected – Agency Activities, Collection Methodology, and Information Management**

### **5(a) Agency Activities**

1. Review and make a preliminary determination of whether business information may be entitled to confidential treatment. This review would be undertaken in response to a FOIA request or when EPA desires to determine the confidentiality of information within its possession for other purposes (e.g., rulemaking, litigation, or an advance confidentiality determination). It would involve determining whether a business confidentiality claim exists or whether a Federal court or an EPA legal office has previously determined that the information in question is entitled to treatment as CBI.
2. Notify the affected business orally and in writing that the Agency is determining the confidentiality of the information and provide the business with an opportunity to comment.
3. Review the substantiation received (if any) and makes a final determination whether the business information in question is entitled to confidential treatment. This determination will be made by the appropriate EPA legal office as described in 40 CFR 2.205.

### **5(b) Collection Methodology and Management**

The types of information that are requested are described under 4(b) above. EPA notifies affected businesses orally and in writing that it is determining the confidentiality of information they have submitted and afford them the opportunity to comment. Affected businesses may submit comments by the date specified in the notice (i.e., postmarked or hand delivered no later than the specified date); or if a request for an extension of the comment period is made by the business and approved by the EPA legal office before the comments are due, the comment period may be extended (40 CFR 2.205(b)(2)).

Confidential information that is submitted to EPA is protected in accordance with the policies and procedures discussed in (1) Chapter 8, “Information Security,” of EPA’s *Information Resources Management (IRM) Policy Manual*, Directive 2100, revised December 20, 1999; (2) the *EPA Information Security Manual*, Directive 2195A1, December 20, 1999; and (3) information security procedures issued by EPA organizations with statutory authority for the information [e.g., EPA’s Office of Prevention, Pesticides, and Toxic Substances has developed specific procedures for protecting the confidentiality of information obtained under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)].

**5(c) Small Entity Flexibility**

EPA does not have the flexibility to waive the need for substantiations from small entities for several reasons: (1) EPA is required to disclose information that is requested under FOIA, unless the information is specifically exempt; (2) if EPA discloses information that is entitled to confidential treatment, the Federal government could be held liable under the Federal Tort Claims Act and individual Federal employees could be subject to criminal liability under the Trade Secrets Act and other statutes, and (3) the submitter of the information is in the best position to explain why particular information should be entitled to confidential treatment.

**5(d) Collection Schedule**

The collection of substantiations occurs on a case-by-case basis, as needed.

**6. Estimating the Burden and Cost of the Collection**

Annual public reporting and recordkeeping burden for this collection of information:  
4.0 hours per response  
Estimated Number of Respondents: 1,320  
Frequency of Response: 1 per year  
Estimated Total Annual Hour Burden: 1,992.30 hours  
Estimated Total Annual Cost: \$88,825.25 includes \$0 annualized capital or O&M costs.

**6(a) Estimating Respondent Burden and Cost**

**A. Substantiation of confidentiality claim**

EPA receives approximately 1,320 FOIA requests for information that is claimed as CBI each year. Yet, formal confidentiality determinations are not always required. For example, after consulting with an individual who requested information under FOIA, the Agency may be able to provide the information that is of most interest to the requester without disclosing any CBI. In other cases, EPA may find that a Federal Court or EPA legal office has previously determined that the information in question is



entitled to confidential treatment, and further examination of the information may not be required.

EPA estimates that in accordance with the procedures outlined in 40 CFR Part 2, subpart B, the Agency would notify 1,320 businesses annually that a final confidentiality determination on information the business has previously claimed as CBI (or which could be expected to be CBI) is being made, and provide them with an opportunity to submit comments explaining why previously submitted information should be treated as confidential. Each affected business then has an opportunity to submit comments explaining why the information should be protected (i.e., substantiation).

EPA estimates that it takes industry approximately 4.00 hours (2.00 attorney hrs., 2.00 manager hrs.) and \$190.44 (\$60.00/attorney hr., \$35.22/manager hr.) in labor to prepare and submit each substantiation; or a total of 1,732 hours at a cost of \$82,460.52 in labor for all 433 substantiations. For those 90 businesses that do not submit substantiations, they are still likely to spend about 1 hour (0.50 manager hr. and 0.50 technical hour) at a cost of \$34.22 (\$35.22/manager hr. and \$33.22/technical hr.) in labor to review EPA's notice, examine the information in question, and make a decision not to respond; or a total of 90 hours at a cost of \$3,079.80 in labor costs for reviewing and deciding not to respond in 90 cases. The total burden on industry to review and, if desired, respond to the EPA substantiation requests is 1,862 hours at a cost of \$85,540.32 in labor.

#### *B. Confidentiality agreements*

When EPA utilizes the services of contractors/subcontractors in implementing 40 CFR, Part 2, subpart B, all contractor/subcontractor employees who may be given access to confidential information must first sign confidentiality agreements stating that they will honor the terms of the contract which requires the protection of CBI. In addition, the contractor/subcontractor businesses must maintain a file of all such agreements. EPA estimates that there are about 129 contractor/subcontractor businesses that handle CBI in connection with their work for EPA each year. These 129 contractor/subcontractor businesses together have a total of approximately 658 employees who must sign confidentiality agreements each year. Each employee would need approximately 0.10 hour to review and sign an agreement, at a cost of \$3.32 in labor (0.10 manager hr. at \$33.22/manager hr.); employees' review and signature of all agreements would require approximately 65.80 hours at a cost of \$2,184.56 in labor per year. In addition, each subcontractor/contractor business would need approximately 0.50 hour at a cost of \$8.53 in labor per year to maintain a file of employee confidentiality agreements (0.50 clerical hr. at \$17.05/clerical hr.); the 129 contractor/subcontractor businesses together would require a total of 64.50 hours at a labor cost of \$1,100.37 to maintain a file of confidentiality agreements. The total burden for signing and maintaining confidentiality agreements would thus be 130.30 hours at a cost of \$3,284.93.

C. *Overall Respondent Burden*

The overall burden for handling confidentiality claims – including the substantiation process and the signing/maintaining of confidentiality agreements – would be 1,992.30 hours at a total labor cost of \$88,825.25 per year. EPA estimates that no capital costs or operation and maintenance costs would be incurred as a result of this information collection.

6(b) **Estimating Agency Burden and Cost**

The burden on EPA involved in evaluating confidentiality claims, notifying affected businesses, and making final confidentiality determinations varies depending on the complexity of the claim. In some cases, the information that industry claims as confidential is specific and easy to identify; yet in other cases, entire reports may be claimed as confidential. In the latter case, a significant amount of time may be required just to review the information in question. In other cases, EPA may be able to satisfy a FOIA request without going through the entire substantiation process, if after conferring with a requestor, the Agency is able to provide the information of interest without releasing CBI.

Based on past experience, EPA estimates that on average, it takes approximately 7 hours (4 attorney hrs., 2 technical hrs., and 1 clerical hour) at a cost of \$284.37 (\$45.99/attorney hr., GS-14, Step 5; \$38.92/technical hr., GS-13, Step 5; and \$22.57/clerical hr., GS-9, Step 5) to conduct an initial review of a confidentiality claim and prepare and request a substantiation from the submitter. Thus, in order to review the information in question and prepare approximately 533 substantiation requests per year, EPA would spend a total of 3,731 hours in staff time at a total labor cost of \$151,569.21.

In addition, after industry comments are received, it takes approximately 8 hours (6 attorney hrs. and 2 technical hrs.) at a cost of \$353.78 (\$45.99/attorney hr., GS-14, Step 5 and \$38.92/technical hr., GS-13, Step 5) to review the comments and determine whether the information that is claimed as confidential is indeed entitled to confidential treatment. It would take EPA a total of 3,544.00 hours at a total labor cost of \$156,724.54 to review the approximately 443 substantiations that would be submitted by industry. (Of the 533 businesses, EPA estimates that approximately 443 businesses would respond by submitting substantiations.)

The total burden to EPA to review the initial information submitted to EPA, make a preliminary determination of confidentiality, request comments from industry, review the substantiations received, and make final confidentiality determinations would be approximately 7,345.00 hours at a total labor cost of \$308,293.75 per year.

6(c) **Bottom Line Burden Hours and Cost**

1. *Substantiation of Confidentiality Claims*

*For 443 Businesses Submitting Substantiations:*

Burden: 4 hrs. x 433 = 1,772 hrs.

Costs: \$190.44 x 433 = \$82,460.52

*For 90 Businesses Deciding Not To Respond:*

Burden: 1 hr. x 90 = 90 hrs.

Costs: \$34.22 x 90 = \$3,079.80

*Totals:*

1,772 + 90 = 1,862 hrs.

\$82,460.52 + 3,079.80 = \$85,540.32

2. *Confidentiality agreements*

*For 658 Contractor/Subcontractor Employees To Review and Sign Confidentiality Agreements:*

Burden: 0.10 hours x 658 respondents/year = 65.80 hrs.

Costs: \$3.32 x 658 = \$2,184.56

*For 129 Contractor/Subcontractor Businesses to Maintain and File Confidentiality Agreements:*

Burden: 0.50 hours x 129 respondents/year = 64.50 hours

Costs: \$8.53 x 129 respondents/year = \$1,100.37

*Totals:*

65.80 hrs. + 64.50 hrs. = 130.30 hrs.

Costs: \$2,184.56 + \$1,100.37 = \$3,284.93

3. *Total Burden and Costs for Respondents:*

Burden: 1,862+ 130.30 = 1992.30 hours

Costs: \$85,540.32 + \$3,284.93 = \$88,825.25

4. *The Agency Tally*

*For Initial Review, Preliminary Determination, and Request for Substantiation:*

Burden: 7 hrs. x 533 = 3,731 hrs.

Costs: \$284.37 x 533 = \$151,569.21

*For Review of Substantiations and Final Confidentiality Determination:*

Burden: 8 hrs. x 443 = 3,544.00 hrs.

Costs: \$353.78 x 443 = \$156,724.54

*Totals:*

Burden: 3,731 hrs. + 3,544 hrs. = 7,275 hrs.  
Costs: \$151,569.21 + \$156,724.54 = \$308,293.75.

5. *Variations in the Annual Bottom Line*

Variations in the annual burden on EPA and respondents could potentially occur due to changes in:

- the number of FOIA requests that EPA receives for information that has been claimed as confidential;
- the number of times that EPA determines that a formal confidentiality determination is necessary and notifies affected businesses, providing them with an opportunity to comment; and
- the number of times that affected businesses decides to submit substantiations.

At this time, EPA does not foresee any significant changes in the annual burdens outlined above.

6(d) **Reasons for Change in Burden**

These has been a decrease of 10 hours in the estimated burden

6(e) **Burden Statement**

The annual public reporting and recordkeeping burden for this collection of information is estimated to average hours for 1,320 respondents, or 1.5 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop; acquire, install, and utilize technology and systems for the purposes of collecting; validating, and verifying information; processing and maintaining information; and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; training personnel to be able to respond to a collection of information; searching data sources; completing and reviewing the collection of information; and transmitting or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public

docket for this ICR under Docket ID No. EPA-HQ-OEI-2010-0746, which is available for online viewing at [www.regulations.gov](http://www.regulations.gov), or in person viewing at the OEI Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the OEI Docket is (202) 566-1752. An electronic version of the public docket is available at [www.regulations.gov](http://www.regulations.gov). This site can be used to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select “search,” then key in the docket ID number identified above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17<sup>th</sup> Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Please include the EPA Docket ID No. (EPA-HQ-OEI-2010-0746) and OMB control number (2020-0003) in any correspondence.