purportedly ''VOC-free'' paints. ''VOC'' is the abbreviation for volatile organic compounds. VOC-free includes claims such as ''zero VOCs,'' ''0 VOCs,'' and ''No VOCs.'' According to the FTC complaint, respondent made unsubstantiated representations that its paints: (1) Are VOC-free; (2) are VOC-free during or immediately after painting; (3) will not emit any chemical or substance, including VOCs, that causes material harm to consumers, including sensitive populations such as children; and (4) will not emit any chemical or substance, including VOCs, during or immediately after painting, that causes material harm to consumers, including sensitive populations such as children. The FTC further alleges that respondent provided independent retailers with promotional materials containing the same claims it made to consumers. Thus, the complaint alleges that respondent engaged in deceptive practices in violation of Section 5(a) of the FTC Act.

The proposed consent order contains three provisions designed to prevent respondent from engaging in similar acts and practices in the future. Part I prohibits emission-free and VOC-free claims unless both content and emissions are actually zero or at trace levels. The orders define ''emission'' to include all emissions (not just VOCs that cause smog). This definition reflects the Commission's Enforcement Policy Statement and consumer expectations: consumers are likely concerned about the potential health effects from exposure to chemical emissions found in indoor air, not just VOCs that affect outdoor air quality. The order defines ''trace level of emission'' to mean (1) no intentionally added VOC, (2) emission of the covered product does not cause material harm that consumers typically associate with emission, including harm to the environment or human health, and (3) emission of the covered product does not result in more than harmless concentrations of and compound higher than would be found under normal conditions in the typical residential home without interior architectural coating. Part II prohibits misleading representations regarding emission, VOC levels, odor, and any general environmental and health benefit of paints. The order requires competent and reliable scientific evidence to substantiate these representations. Part IV prohibits respondent from providing third parties with the means and instrumentalities to make false, unsubstantiated, or otherwise misleading representations of material fact regarding paints, including any representation prohibited by Parts I or II.

To correct existing unsubstantiated zero emission and VOC claims, Part III requires the respondent to send letters to its dealers and distributors, instructing them to put stickers on paint cans to obscure allegedly unsubstantiated emission and VOC claims.

Parts V through IX are reporting and compliance provisions. Part V mandates that respondent acknowledge receipt of the order, distribute the order to certain employees and agents, and secure acknowledgments from recipients of the order. Part VI requires that respondent submit compliance reports to the FTC within sixty (60) days of the order's issuance and submit additional reports when certain events occur. Part VII requires that respondent must create and retain certain records for five (5) years. Part VIII provides for the FTC's continued compliance monitoring of respondent's activity during the order's effective dates. Part IX is a provision ''sunsetting'' the order after twenty (20) years, with certain exceptions.

If the Commission finalizes the agreement's proposed order, it plans to propose harmonizing with this order the consent orders issued in the PPG Architectural Finishes, Inc. (Docket No. C–4385) and The Sherwin-Williams Company (Docket No. C–4386) matters. Specifically, the Commission plans to issue orders to show cause why those matters should not be modified pursuant to Section 3.72(b) of the Commission Rules of Practice, 16 CFR 3.72(b).

The purpose of the analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2017–14973 Filed 7–17–17; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–0040]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry; How To Prepare a Pre-Request for Designation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 17, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910—NEW and title ''Draft Guidance for Industry; How to Prepare a Pre-Request for Designation (Pre-RFD).'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Draft Guidance for Industry; How To Prepare a Pre-Request for Designation (Pre-RFD)

OMB Control Number 0910—NEW

Since its establishment on December 24, 2002, the FDA Office of Combination Products (OCP) has served as a resource for sponsors at various stages of development of their product. Sponsors often seek OCP feedback on whether their medical product will be regulated as a drug, a device, a biologic,

or a combination product, and which FDA medical product Agency Center (Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, or Center for Devices and Radiological Health) will regulate it, if it is a non-combination product, or will have the primary jurisdiction for the premarket review and regulation of the product, if it is a combination product.

There are two ways that a sponsor can receive such feedback from OCP. One option is to submit an RFD to receive a formal, binding determination for the sponsor's product with respect to classification and/or center assignment that may be changed under conditions specified in section 563 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–2) and 21 CFR 3.9 in the regulations. The RFD process is codified in 21 CFR part 3, and OCP has issued a guidance about this process (see ''How to Write a Request for Designation'' at *https://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm*). A second more flexible option is for a sponsor to submit an inquiry to OCP to receive a preliminary jurisdictional assessment, which is not binding.

Many sponsors seek to utilize the flexibility of more approachable ways to interact with OCP and the medical product Agency Centers to obtain feedback from the Agency before submitting a marketing application to the Agency. Over time, these informal methods of obtaining feedback have become increasingly customary with sponsors, and for some, even preferable to the formal RFD process. Accordingly, FDA is enhancing the transparency and consistency of this process, which will now be called the ''Pre-Request for Designation (Pre-RFD) Program.''

This draft guidance describes this structured process with clear recommendations for sponsors wishing to submit Pre-RFDs. It also provides the process for review of Pre-RFDs by FDA staff, the general timeframes for sponsors to receive feedback from OCP, and the process for scheduling teleconferences and meetings in relation to a Pre-RFD.

This draft guidance describes how to prepare a Pre-RFD. The guidance provides recommendations regarding the information that should be submitted in a Pre-RFD request and procedures that should be followed for meetings or conference calls between OCP, the Centers, and industry representatives or sponsors.

The proposed collections of information are necessary to allow the Agency to receive Pre-RFD requests in order to implement this voluntary submission program.

In the **Federal Register** of January 13, 2017 (82 FR 4351), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, they were not responsive to the four collection of information topics solicited and therefore will not be discussed.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pre-RFD Submissions	136	1	136	12	1,632
Pre-RFD Meetings	136	1	136	1	136
Total					1,768

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

Dated: July 12, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–15005 Filed 7–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0600]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Drug User Fee Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 17, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0539. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Animal Drug User Fee Cover Sheet OMB Control Number 0910–0539—Extension

Under section 740 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j–12), FDA has the authority to assess and collect application fees from each person who submits certain new animal drug applications or certain supplemental animal drug applications. The Animal Drug User Fee cover sheet (Form FDA 3546) is designed to collect the minimum necessary information to determine whether a fee is required for the review of an application or supplement or whether an application fee waiver was granted, to determine the amount of the fee required, and to assure that each animal drug user fee payment is appropriately linked to the