Estimated annual cost: $7,920,000, includes $91,300 annualized capital or O&M costs.

Changes in estimates: There is no change in burden from the previous ICR.

(22) *Docket ID Number:* EPA–HQ–OECA–2013–0323; NESHAP for Area Sources: Electric Arc Furnace Steelmaking Facilities (40 CFR part 63, subpart YYYYY) (Renewal); EPA ICR Number 2277.06; OMB Control Number 2060–0608; Expiration date August 31, 2021.

Respondents: Electric Arc Furnace (EAF) Steelmaking facilities that are area sources of HAP emissions.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart YYYYY).

Estimated number of respondents: 91.

Frequency of response: Initially, occasionally, and semiannually.

Estimated annual burden: 4,450 hours.

Estimated annual cost: $467,000, includes $0 annualized capital or O&M costs.

Changes in estimates: There is no change in burden from the previous ICR.

(23) *Docket ID Number:* EPA–HQ–OECA–2014–0027; NSPS for Bulk Gasoline Terminals (40 CFR part 60, subpart XX) (Renewal); EPA ICR Number 0664.13; OMB Control Number 2060–0006; Expiration date September 30, 2021.

Respondents: Bulk gasoline terminal facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart XX).

Estimated number of respondents: 40.

Frequency of response: Initially.

Estimated annual burden: 13,200 hours.

Estimated annual cost: $1,390,000, includes $0 annualized capital or O&M costs.

Changes in estimates: There is no change in burden from the previous ICR.

(24) *Docket ID Number:* EPA–HQ–OECA–2014–0099; NESHAP for Ferroalloys Production Area Sources (40 CFR part 63, subpart YYYYYY) (Renewal); EPA ICR Number 2303.06; OMB Control Number 2060–0625; Expiration date September 30, 2021.

Respondents: Ferroalloys production facilities that are area sources of HAP emissions.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart YYYYYY).

Estimated number of respondents: 10.

Frequency of response: Initially and annually.

Estimated annual burden: 391 hours.

Estimated annual cost: $41,100, includes $0 annualized capital or O&M costs.

Changes in estimates: There is no change in burden from the previous ICR.

Martha Segall,

Acting Director, Monitoring, Assistance and Media Programs Division, Office of Compliance.

[FR Doc. 2020–10097 Filed 5–11–20; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK OF THE UNITED STATES

Sunshine Act Meeting; Notice of an Open Meeting of the Board of Directors of the Export-Import Bank of the United States

TIME AND DATE: Thursday, May 21, 2020 at 10:00 a.m.

PLACE: The meeting will be held via Teleconference.

STATUS: The meeting will be open to public observation by teleconference.

MATTER TO BE CONSIDERED:

- Item No. 1 Small Business Update.
- Item No. 2 Additionality and Economic Impact Reforms.

CONTACT PERSON FOR MORE INFORMATION: Members of the public who wish to attend the meeting should email Joyce Stone, Office of the General Counsel, 811 Vermont Avenue NW, Washington, DC 20571 (*joyce.stone@exim.gov*) by close of business Tuesday, May 19, 2020. Individuals will be given call-in information upon notice of attendance to EXIM.

Joyce Stone,

Assistant Corporate Secretary.

[FR Doc. 2020–10220 Filed 5–8–20; 11:15 am]

BILLING CODE 6690–01–P

FEDERAL TRADE COMMISSION

[File No. 191 0169]

AbbVie Inc. and Allergan plc; Analysis of Consent Order To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before June 11, 2020.

ADDRESSES: Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write: ''AbbVie and Allergan; File No. 191 0169'' on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Kari Wallace (202–326–3085), Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis of Agreement Containing Consent Orders to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC website (for May 5, 2020), at this web address: *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before June 11, 2020. Write ''AbbVie and Allergan; File No. 191 0169'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Due to the public health emergency in response to the COVID–19 outbreak and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your

comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write ''AbbVie and Allergan; File No. 191 0169'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http://www.ftc.gov* to read this Notice and the news release describing this matter. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before June 11, 2020. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Consent Order To Aid Public Comment

I. Introduction

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from AbbVie Inc. (''AbbVie'') and Allergan plc (''Allergan'') designed to remedy the anticompetitive effects resulting from AbbVie's proposed acquisition of Allergan. The proposed Decision and Order (''Order'') contained in the Consent Agreement requires Allergan to divest all rights and assets related to its Zenpep and Viokase products to Nestlé S.A. (''Nestlé''). The proposed Order also requires that Allergan return its rights and assets related to brazikumab to AstraZeneca plc (''AstraZeneca'').

The proposed Consent Agreement has been placed on the public record for thirty days so that interested persons may submit comments. Comments received during this period will become part of the public record. After thirty days, the Commission will review the comments received and decide whether it should withdraw, modify, or make the Consent Agreement final.

Pursuant to a Scheme of Arrangement under Irish law, AbbVie will acquire all of the voting securities of Allergan from its shareholders for approximately $63 billion (the ''Acquisition''). The Commission's Complaint alleges that the proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by substantially lessening competition in the U.S. markets for (1) prescription drugs for the treatment of exocrine pancreatic insufficiency (''EPI''); (2) Interleukin-23 (''IL–23'') inhibitors for the treatment of moderate-to-severe Crohn's disease; and (3) IL–23 inhibitors for the treatment of moderate-to-severe ulcerative colitis. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be lost in these markets as a result of the proposed Acquisition.

II. The Parties

Headquartered in North Chicago, Illinois, AbbVie researches, develops, manufactures, and sells prescription pharmaceutical products and biologic products in several therapeutic areas, including immunology, oncology, virology, neuroscience, and women's health. Among other products, AbbVie sells a product to treat EPI and is developing an IL–23 inhibitor to treat moderate-to-severe Crohn's disease and ulcerative colitis. Like AbbVie, Allergan researches, develops, manufactures, and sells prescription pharmaceutical products in the United States. Among its products, Allergan also sells a product to treat EPI and is developing an IL–23 inhibitor to treat moderate-to-severe Crohn's disease and ulcerative colitis.

III. The Relevant Products and Structure of the Markets

A. Drugs for the Treatment of Exocrine Pancreatic Insufficiency

EPI is a condition that results from a deficiency of pancreatic enzymes. Patients who have EPI cannot properly digest fats, proteins, and carbohydrates in the foods they eat and, as a result, may suffer from malnutrition and have uncomfortable gastrointestinal symptoms when they eat. EPI is treated using pancreatic enzyme products. Pancreatic enzyme products contain the active ingredient pancrelipase, a mixture of the digestive enzymes amylase, lipase, and protease that is extracted from the pancreas of a pig.

Only four companies sell prescription pancreatic enzyme product in the United States: AbbVie, Allergan, Vivus Inc. (''Vivus''), and Chiesi USA, Inc. (''Chiesi''). AbbVie is the clear market leader with its product, Creon, and Allergan is the second-largest supplier, with its product, Zenpep. Vivus sells Pancreaze and Chiesi sells Pertzye. Allergan also sells a second pancreatic enzyme product, Viokase, although its sales in the United States are much more limited. Together, AbbVie and Allergan have a share of more than 95

percent of the market for drugs to treat EPI.

B. Interleukin-23 Inhibitors for the Treatment of Moderate-to-Severe Crohn's Disease and for the Treatment of Moderate-to-Severe Ulcerative Colitis

Ulcerative colitis and Crohn's disease are the most common causes of chronic inflammation of the digestive tract. Both diseases have similar symptoms—severe diarrhea, abdominal pain, fatigue, and weight loss—and both can be debilitating and lead to life-threatening complications. The location of the inflammation is the primary difference between the two diseases: Ulcerative colitis is a continuous inflammation of the colon, affecting only the innermost lining, while Crohn's disease can occur anywhere between the mouth and the anus, has healthy parts of the digestive tract between inflamed parts, and can occur in all layers of the bowel walls. Because the diseases are similar, drugs that are effective in treating ulcerative colitis are also typically effective in treatment Crohn's disease (and vice versa), but the United States Food and Drug Administration (''FDA'') requires that companies seeking ulcerative colitis and Crohn's disease indications for drugs conduct separate clinical studies and submit separate applications to market drugs for each indication.

Various drugs are approved to treat ulcerative colitis and Crohn's disease, but the effectiveness for most drugs is limited. IL–23 inhibitors are a new class of drugs to treat both diseases. Johnson & Johnson's Stelara is the only IL–23 inhibitor currently approved to treat moderate-to-severe Crohn's disease and ulcerative colitis in the United States. Stelara is both an IL–23 inhibitor and an Interleukin-12 inhibitor. Only three other companies—AbbVie, Allergan, and Eli Lilly and Company—have IL–23 inhibitors in late-stage development for ulcerative colitis and Crohn's disease. Allergan is developing brazikumab and AbbVie is developing Skyrizi.

IV. The Relevant Geographic Market

The United States is the relevant geographic market in which to assess the competitive effects of the proposed Acquisition. Drugs to treat EPI and drugs to treat moderate-to-severe ulcerative colitis and Crohn's disease are prescription pharmaceutical products and regulated by FDA. As such, products sold outside the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

V. Competitive Effects of the Acquisition

The proposed Acquisition would likely result in substantial competitive harm to consumers in the markets for prescription drugs for the treatment of EPI, IL–23 inhibitors for the treatment of moderate-to-severe Crohn's disease, and IL–23 inhibitors for the treatment of moderate-to-severe ulcerative colitis. Together, AbbVie and Allergan account for more than 95 percent of the market for drugs to treat EPI, and they are two of a limited number of companies in late-stage development with IL–23 inhibitors to treat moderate-to-severe ulcerative colitis and Crohn's disease.

VI. Entry Conditions

Entry in the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed Acquisition. New entry would require significant investment of time and money for product research and development, regulatory approval by the FDA, developing clinical history supporting the long-term efficacy of the product, and establishing a U.S. sales and service infrastructure. Such development efforts are difficult, time-consuming, and expensive, and often fail to result in a competitive product reaching the market.

VII. The Consent Agreement

The Consent Agreement eliminates the competitive concerns raised by the proposed Acquisition by requiring the combined company to divest Allergan's Zenpep and Viokase business, including its regulatory approvals, intellectual property, contracts, and inventory to Nestlé, and Allergan's brazikumab business to AstraZeneca. AbbVie and Allergan also must transfer all business information, research and development information, regulatory, formulation, and manufacturing reports related to the divested products, as well as provide access to knowledgeable employees to assist in the transfer. The provisions of the Consent Agreement ensure that Nestlé and AstraZeneca become independent, viable, and effective competitors in the U.S. markets.

Nestlé is the world's largest food and beverage company, operating in more than 190 countries around the world. While the company is most well-known for its chocolate products, it also operates Nestlé Health Science, an integrated health company that focuses on nutrition products, including enteral feeding products that are used in hospitals and at home by patients who are unable to chew or swallow food. Nestlé's existing business includes products that are highly complementary to the divestiture assets. Nestlé has the expertise, U.S. sales infrastructure, and resources to restore the competition that otherwise would have been lost due to the proposed Acquisition.

AstraZeneca is a global research-based pharmaceutical company specializing in researching, developing, manufacturing, and marketing prescription products. AstraZeneca was responsible for conducting some of the early phase clinical studies for brazikumab, but out-licensed the product to Allergan in 2016. AstraZeneca is a well-qualified buyer for brazikumab because, as the original innovator of the product, it already has experience developing brazikumab prior to out-licensing it to Allergan, and, further, the key team members who were previously responsible for brazikumab's development are still employed by the company and will take responsibility for the developing the product. With its resources, capabilities, and previous experience with brazikumab, AstraZeneca is well positioned to successfully develop and commercialize the product and thereby replace the competition that otherwise would have been lost through the proposed Acquisition.

AbbVie and Allergan must accomplish the divestitures no later than ten days after consummating the proposed Acquisition. If the Commission determines that Nestlé or AstraZeneca are not acceptable acquirers, or that the manner of the divestitures is not acceptable, the proposed Order requires AbbVie and Allergan to unwind the sale of rights and assets and then divest the affected product to a Commission-approved acquirer within six months of the date the Order becomes final. The Commission has agreed to appoint a Monitor to ensure that AbbVie and Allergan comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to the buyers. The proposed Order further allows the Commission to appoint a trustee in the event that AbbVie and Allergan fail to divest the products as required.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and 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.

April J. Tabor,

Acting Secretary.

[FR Doc. 2020–10081 Filed 5–11–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–8003]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. 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 or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by July 13, 2020.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-8003 1915(c) Home and Community Based Services (HCBS) Waiver

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. The term ''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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* 1915(c) Home and Community Based Services (HCBS) Waiver; *Use:* We will use the web-based application to review and adjudicate individual waiver actions. The web-based application will also be used by states to submit and revise their waiver requests. *Form Number:* CMS–8003 (OMB control number 0938–0449); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 47; *Total Annual Responses:* 71; *Total Annual Hours:* 6,005. (For policy questions regarding this collection contact Kathy Poisal at 410–786–5940.)

Dated: *May 7, 2020.*

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–10095 Filed 5–11–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–D–1106, FDA–2020–D–1137, FDA–2020–D–1138, FDA–2020–D–1139, and FDA–2020–D–1140]

Guidance Documents Related to Coronavirus Disease 2019 (COVID–19); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of FDA guidance documents related to the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE). This notice is pursuant to the process that FDA announced, in the **Federal Register** of March 25, 2020, for making available to the public COVID–19-related guidances. The guidances identified in this notice address issues related to the COVID–19 PHE and have been issued in accordance with the process announced in the March 25, 2020, document. The guidance documents have been implemented without prior comment, but they remain subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidances is published in the **Federal Register** on May 12, 2020. The guidance documents have been implemented without prior comment, but they remain subject to comment in accordance with the Agency's good guidance practices.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows: