performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collection

Report title: Recordkeeping and Disclosure Requirements Associated with Regulation II.

Agency form number: FR II.

OMB control number: 7100–0349.

Frequency: On occasion.

Respondents: State member banks, national banks, insured nonmember banks, savings associations, and federally-chartered credit unions.

Estimated number of respondents: Implement policies and procedures, 1; Review and update policies and procedures, 527; General recordkeeping, 527; Annual notification and change in status, 527.

Estimated average hours per response: Implement policies and procedures, 160; Review and update policies and procedures, 40; General recordkeeping, 1; Annual notification and change in status, 1.

Estimated annual burden hours: Implement policies and procedures, 160; Review and update policies and procedures, 21,080; General recordkeeping, 527; Annual notification and change in status, 527.

General description of report: Regulation II—Debit Card Interchange Fees and Routing (12 CFR part 235) implements, among other things, standards for assessing whether interchange transaction fees for electronic debit transactions are reasonable and proportional to the cost incurred by the issuer with respect to the transaction, as required by section 920(a) of the Electronic Fund Transfer Act (EFTA) (15 U.S.C. 1693o–2(a)).

Regulation II limits the interchange transaction fee that covered issuers (issuers that, together with affiliates, have assets of $10 billion or more) can charge for electronic debit transactions. Under the rule, a covered debit card issuer is allowed to receive or charge an interchange transaction fee in the amount of 21 cents plus 5 basis points multiplied by the value of the transaction. In addition, a covered issuer may receive or charge an amount of no more than 1 cent per transaction (the ''fraud-prevention adjustment'') for the costs associated with preventing fraudulent electronic debit transactions (fraud-prevention adjustment) if the issuer complies with the standards and requirements set forth in the rule. In addition to these interchange fee provisions, Regulation II prohibits any issuer (*i.e.,* not just covered issuers) or payment card network from directly or indirectly restricting the number of payment card networks on which an electronic debit transaction may be processed to less than two unaffiliated networks, and from directly or indirectly inhibiting the ability of a merchant to direct the routing of electronic debit transactions for processing over any payment card network that may process such transactions. Finally, Regulation II prohibits any issuer from receiving net compensation from a payment card network with respect to electronic debit transactions or debit card-related activities within a calendar year.

Legal authorization and confidentiality: The Recordkeeping and Disclosure Requirements Associated with Regulation II are authorized by section 920(a)(3) of the EFTA.[1] The fraud-prevention and disclosure requirements are additionally authorized by section 920(a)(5) of the EFTA.[2] Regulation II's general recordkeeping requirement for issuers is mandatory. Regulation II's fraud-prevention recordkeeping requirements and disclosure requirements are required to obtain a benefit.

The Recordkeeping and Disclosure Requirements Associated with Regulation II are generally not submitted to the Board or to any of the federal financial regulatory agencies. In the event that the Board obtains such information, it may be kept confidential under exemption 4 of the Freedom of Information Act (FOIA) to the extent that it contains commercial or financial information both customarily and actually treated as private.[3] If such information is obtained through the examination or enforcement process, it may be kept confidential under exemption 8 of the FOIA.[4]

Board of Governors of the Federal Reserve System, November 29, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–26319 Filed 12–2–21; 8:45 am]

BILLING CODE 6210–01–P

[1] 15 U.S.C. 1693*o*–2(a)(3) (authorizing the Board to prescribe regulations regarding interchange transaction fees and require issuers or payment card networks to provide to the Board such information as deemed necessary).

[2] 15 U.S.C. 1693*o*–2(a)(5) (permitting the Board to allow for the fraud-prevention adjustment and condition it upon compliance with fraud-related standards promulgated by the Board).

[3] 5 U.S.C. 552(b)(4).

[4] 5 U.S.C. 552(b)(8).

FEDERAL TRADE COMMISSION

[File No. 211 0101/Docket No. C–4754]

ANI/Novitium; Analysis of Agreement Containing Consent Orders 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 of Proposed Consent Orders to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before January 3, 2022.

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: ''ANI/Novitium; File No. 211 0101'' 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, 400 7th Street SW, Washington, DC 20024.

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 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 January 3, 2022. Write ''ANI/Novitium; File No. 211 0101'' 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 protective actions in response to the COVID–19 pandemic and the agency's heightened security screening, postal mail addressed to the Commission will be delayed. 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 ''ANI/Novitium; File No. 211 0101'' 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 your comment does not include any sensitive or confidential information. In particular, your comment should not include 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 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 *https://www.regulations.gov*—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that 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 *https://www.ftc.gov* to read this Notice and the news release describing this matter. The FTC Act and other laws 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 it receives on or before January 3, 2022. 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 Agreement Containing Consent Orders To Aid Public Comment

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from ANI Pharmaceuticals, Inc. (''ANI'') and Novitium Pharma LLC and Esjay LLC (collectively, ''Novitium'') designed to remedy the anticompetitive effects resulting from ANI's acquisition of the non-corporate interests of Novitium. Pursuant to an agreement dated March 8, 2021, ANI proposes to acquire Novitium in a transaction valued at approximately $210 million. The Commission alleges in its Complaint 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 lessening future competition in the following two U.S. markets: (1) Generic SMX–TMP oral suspension; and (2) generic dexamethasone tablets. The Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Acquisition.

Under the terms of the proposed Decision and Order (''Order''), Respondents are required to divest all of ANI's rights and assets related to the following two products to Prasco LLC (''Prasco''): (1) Generic sulfamethoxazole-trimethoprim (''SMX–TMP'') oral suspension; and (2) generic dexamethasone tablets. The Commission and Respondents have agreed to an Order to Maintain Assets that requires Respondents to operate and maintain each divestiture product in the normal course of business until the products are ultimately divested to Prasco. The Commission also issued the Order to Maintain Assets.

The Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the Consent Agreement, modify it, or make final the proposed Order.

I. The Respondents

Respondent ANI is a public specialty pharmaceutical company headquartered in Baudette, Minnesota selling both branded and generic pharmaceutical products.

Respondent Novitium is a privately-held company based in East Windsor, New Jersey. The company develops, manufactures, and commercializes generic pharmaceutical products.

II. The Products and Structure of the Markets

In human pharmaceutical markets, price(s) generally decreases as the number of generic competitors increase. Prices continue to decrease incrementally with the entry of the second, third, fourth, and further pharmaceutical competitors. Accordingly, a reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing.

The Proposed Acquisition would reduce future competition in the SMX–TMP oral suspension market, where ANI is a current competitor and Novitium is likely to enter the market. Generic SMX–TMP oral suspension is an antibiotic product used to treat a variety of infections. Five companies, including ANI, currently market the product in the United States, but at least one has had difficulty manufacturing the product. Novitium is one of a limited number of suppliers capable of entering the market for SMX–TMP oral suspension in the near future.

Similarly, the Proposed Acquisition would reduce future competition in the 4 mg strength of generic dexamethasone tablets market, where both ANI and Novitium are likely to enter the market in the near future. Generic dexamethasone tablets are an oral steroid product used to treat inflammation associated with a variety of conditions. Dexamethasone tablets are available in a variety of strengths, although the most widely used strength is the 4 mg strength. Only two companies sell the 4 mg strength of dexamethasone tablets in the United States today, and ANI and Novitium are two of a limited number of companies likely to enter the market in the near future.

III. Entry

Entry into the two markets at issue would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including approval by the FDA, is costly and lengthy.

IV. Competitive Effects

The Proposed Acquisition likely would delay or reduce the introduction of beneficial competition, and subsequent price decreases, by eliminating future competition in the two markets at issue. While five companies, including ANI, currently market the generic SMX–TMP product in the United States, at least one has had difficulty manufacturing the product, and Novitium is one of a limited number of suppliers capable of entering the market in the near future. In the generic dexamethasone tablets market, only two companies sell the 4 mg strength in the United States today and ANI and Novitium are two of a limited number of companies entering the market in the near future. Absent a remedy, the Proposed Acquisition likely would cause U.S. consumers to pay higher prices for the aforementioned generic products.

V. The Proposed Order and the Order To Maintain Assets

The proposed Order and the Order to Maintain Assets effectively remedy the competitive concerns raised by the Proposed Combination for the two generic pharmaceutical product areas at issue. Pursuant to the proposed Order, the parties are required to divest ANI's rights and assets related to the two products to Prasco. The parties must accomplish these divestitures no later than ten days after the Proposed Combination is consummated. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products.

While ANI and Novitium do not compete again each other in the market for generic erythromycin and ethylsuccinate granules for oral suspension, Novitium has an unexecuted option to acquire a product from another company and ANI sells a product today. The proposed Order requires prior Commission approval before ANI or Novitium may acquire any rights or interests in certain products containing, as the active pharmaceutical ingredients, erythromycin and ethylsuccinate. This provision allows the Commission to evaluate whether a future acquisition of the erythromycin and ethylsuccinate product would reduce competition at the time the acquisition is proposed. The proposed Order also requires ANI and Novitium to seek Commission approval before acquiring any other SMX–TMP or dexamethasone tablet product.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Combination. Prasco is a capable purchaser with management and employees who have experience marketing and distributing generic pharmaceutical products. It will be able to replicate the competition otherwise lost from the Proposed Combination.

The proposed Order contains several provisions to help ensure the divestitures are successful. ANI will supply Prasco with SMX–TMP oral suspension and dexamethasone tablets for up to three years while the company transfers the manufacturing technology to Prasco's contract manufacturing designee. The proposed Order also requires ANI to provide transitional services to Prasco to assist it in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. These transitional services include technical assistance to have the products manufactured in substantially the same manner and quality employed or achieved by ANI. It also includes advice and training from knowledgeable employees of the parties. Further, the proposed Order requires prior Commission approval before Prasco may sell, license, or otherwise convey any of the assets divested pursuant to the proposed Order.

Under the proposed Order, the Commission also will appoint a Monitor to ensure ANI and Novitium comply with their obligations under the proposed Order and Order to Maintain Assets. The Commission has appointed Denise Smart of Smart Consulting Group, LLC as the Monitor. Ms. Smart is an expert in areas such as pharmaceutical R&D, regulatory approval, manufacturing and supply, and marketing, and she has over thirty years of experience in the pharmaceutical area and has provided consulting services in healthcare business development to major pharmaceutical companies, biotechnology companies, universities, and other government agencies, including the FDA, Department of Defense, and Health and Human Services.

The proposed Order also contains a prior approval provision relating to Prasco, which prohibits Prasco from selling the acquired products for a combined period of ten years after the Order is issued, except to an acquirer that receives the prior approval of the Commission.

The purpose of this analysis is to facilitate public comment on the Consent Agreement and proposed Order to aid the Commission in determining whether it should make the proposed Order final. This analysis is not an official interpretation of the proposed

Order and does not modify its terms in any way.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2021–26294 Filed 12–2–21; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CK–22–003, Emerging Infections Sentinel Networks (EISN) Research; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CK–22–003, Emerging Infections Sentinel Networks (EISN) Research; January 11, 2022, 10:00 a.m.–5:00 p.m., EST, Teleconference, Centers for Disease Control and Prevention, Room 1080, 8 Corporate Square Boulevard, Atlanta, Georgia 30329–4027, in the original FRN. The meeting was published in the **Federal Register** on November 8, 2021, Volume 86, Number 213, page 61767.

The meeting is being amended to change the contact information and should read as follows:

FOR FURTHER INFORMATION CONTACT: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, CDC, 1600 Clifton Road NE, Mailstop US8–1, Atlanta, Georgia 30329–4027, Telephone: (404) 718–8833; Email: *GAnderson@cdc.gov.*

The meeting is closed to the public.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–26298 Filed 12–2–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Health Statistics (BSC, NCHS)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Board of Scientific Counselors, National Center for Health Statistics (BSC, NCHS). This meeting is open to the public.

DATES: The meeting will be held on February 10, 2022, from 11:00 a.m. to 5:15 p.m., EST (times subject to change).

ADDRESSES: Instructions to access the meeting are posted here: *https://www.cdc.gov/nchs/about/bsc/bsc_meetings.htm.*

FOR FURTHER INFORMATION CONTACT: Rebecca Hines, M.H.S., Executive Secretary, NCHS/CDC, Board of Scientific Counselors, 3311 Toledo Road, Room 2627, Hyattsville, Maryland 20782, Telephone: (301) 458–4717; Email: *RSHines@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The Board is charged with providing advice and making recommendations to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NCHS, regarding the scientific and technical program goals and objectives, strategies, and priorities of NCHS.

Matters to be Considered: The meeting agenda will include welcome remarks and a Center update by the NCHS Director; a welcome and introductions for five new Board members who will be attending their first BSC meeting; discussion with members on plans and potential revisions to NCHS surveys, including the addition of new questions; a report out from the Population Health Survey Planning, Methodology and Data Presentation (PHSPMDP) Workgroup on their assessment of the use of panel survey data by NCHS; an update on approaches to enhancing identification of opioid-Involved hospitalizations with clinical data and notes from electronic health records, and; an update on several NCHS Programs. Agenda items are subject to change as priorities dictate.

Meeting Information: Please visit the BSC website for details: *https://www.cdc.gov/nchs/about/bsc/bsc_meetings.htm* for more information on the meeting agenda, including instructions for accessing the live meeting broadcast.

The Board will reserve time for public comment at the end of the day.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–26317 Filed 12–2–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970–0167]

Proposed Information Collection Activity; ACF–801: Child Care and Development Fund (CCDF) Quarterly Case-Level Report

AGENCY: Office of Child Care, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Child Care (OCC), Administration for Children and Families (ACF) is requesting a 3-year extension of the form ACF–801: CCDF Quarterly Case-Level Report (OMB #0970–0167, expiration 2/28/2022). OCC proposes minor changes to the response categories under the following three data elements: Child's gender, ethnicity, and race.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.