[BILLING CODE: 6750-01S]

FEDERAL TRADE COMMISSION

[File No. 192 3050]

Ortho-Clinical Diagnostics, Inc.; Analysis of Proposed 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 or deceptive acts or practices. 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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*].

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. Write "Ortho-Clinical Diagnostics, Inc.; File No. 192 3050" 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, 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: Kenneth Abbe (310-824-4300), Bureau of Consumer Protection, 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 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 March 30, 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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]. Write "Ortho-Clinical Diagnostics, Inc.; File No. 192 3050" 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 "Ortho-Clinical Diagnostics, Inc.; File No. 192 3050" 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 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 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 it. 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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]. 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 Proposed Consent Order to Aid Public Comment

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an agreement containing a consent order from Ortho-Clinical Diagnostics, Inc. ("Ortho" or "Respondent").

The proposed consent order ("proposed order") has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

This matter concerns alleged false or misleading representations that Ortho made concerning its participation in the Privacy Shield framework agreed upon by the U.S. and the European Union ("EU"). The Privacy Shield framework allows for the lawful transfer of personal data from the EU to participating companies. The framework consists of a set of principles and related requirements that have been deemed by the European Commission as providing "adequate" privacy protection. The principles include notice; choice; accountability for onward transfer; security; data integrity and purpose limitation; access; and recourse, enforcement, and liability. The related requirements include, for example, securing an independent recourse mechanism to handle any disputes about how the company handles information about EU citizens.

To participate in the framework, a company must comply with the Privacy Shield principles and self-certify that compliance to the U.S. Department of Commerce ("Commerce"). Commerce reviews companies' self-certification applications and maintains a public website, https://www.privacyshield.gov/list, where it posts the names of companies who have completed the requirements for certification. Companies are required to recertify every year in order to continue benefitting from Privacy Shield.

Ortho markets and sells medical devices and in vitro diagnostics services to the

global clinical laboratory and immunohematology communities. It collects personal data from its suppliers and capital customers around the world, including from EU citizens. According to the Commission's complaint, from approximately September 2017 until March 2019, Ortho published on its website, https://www.orthoclinicaldiagnostics.com/en-us/home/privacy-policy, a privacy policy containing statements related to its participation in Privacy Shield.

The Commission's proposed three-count complaint alleges that Respondent violated Section 5(a) of the Federal Trade Commission Act. Specifically, the first count in the proposed complaint alleges that Respondent engaged in a deceptive act or practice by falsely representing that it was a certified participant in the EU-U.S. Privacy Shield Framework. The second count alleges that Ortho did not verify the truth of the Privacy Shield assurances in its privacy policy, either through a self-assessment or a third party compliance review, so its representation that it "complied with" the Privacy Shield principles was false. Finally, the third count alleges that Ortho failed to annually affirm to Commerce that Ortho will continue to apply the Privacy Shield Principles to personal data it received while it was part of the framework after it withdraws from Privacy Shield.

Part I of the proposed order prohibits the Respondent from making misrepresentations about its membership in any privacy or security program sponsored by the government or any other self-regulatory or standard-setting organization, including, but not limited to, the EU-U.S. Privacy Shield framework and the Swiss-U.S. Privacy Shield framework. Part II also specifically requires the Respondent to comply with the Privacy Shield requirement to continue to protect personal information received

while in the framework.

Parts III through VI of the proposed order are reporting and compliance provisions. Part III requires acknowledgement of the order and dissemination of the order now and in the future to persons with responsibilities relating to the subject matter of the order. Part IV ensures notification to the FTC of changes in corporate status and mandates that the Respondent submit an initial compliance report to the FTC. Part V requires the Respondent to create certain documents relating to its compliance with the order for ten years and to retain those documents for a five-year period. Part VI mandates that the Respondent make available to the FTC information or subsequent compliance reports, as requested.

Part VII is a provision "sun-setting" the order after twenty years, with certain exceptions.

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

By direction of the Commission.

April J. Tabor,

Acting Secretary.

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