

The Relevant Geographic Market

The relevant geographic market for point-of-care blood gas testing systems and point-of-care cardiac marker testing systems is the United States. These products are medical devices regulated by the U.S. Food and Drug Administration (“FDA”). Medical devices sold outside of the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

Competitive Effects of the Acquisition

The proposed Acquisition would likely result in significant competitive harm to consumers in the markets for point-of-care blood gas testing systems and point-of-care cardiac marker testing systems. In each relevant market, customers are able to leverage Abbott and Alere against each other to obtain better prices and improved products. By eliminating this direct and substantial head-to-head competition, the proposed Acquisition likely would allow the combined firm to exercise market power unilaterally, resulting in higher prices, reduced innovation, and less choice for consumers.

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, and establishment of 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.

The Consent Agreement

The Consent Agreement eliminates the competitive concerns raised by the proposed Acquisition by requiring Alere to divest: (1) Its point-of-care blood gas testing business, including its Ottawa, Canada facilities, to Siemens; and (2) its point-of-care cardiac marker testing business, including its San Diego, California facility, to Quidel. Alere must divest all assets and rights to research, develop, manufacture, market, and sell its point-of-care blood gas testing and point-of-care cardiac marker testing product lines, including all related intellectual property and other confidential business information. Further, Siemens and Quidel intend to hire substantially all of Alere’s employees whose responsibilities primarily relate to the research,

development, manufacture, or sale of the relevant products. The provisions of the Consent Agreement ensure that Siemens and Quidel become independent, viable, and effective competitors in the respective markets in order to maintain the competition that currently exists.

Siemens is a global conglomerate with a healthcare division that is one of the world’s largest suppliers of technology to the healthcare industry and a leader in medical imaging and laboratory diagnostics. Siemens currently supplies a benchtop blood gas testing system, and Alere’s handheld system will be highly complementary to Siemens’ portfolio in the United States. Siemens has the expertise, U.S. sales infrastructure, and resources to restore the competition that otherwise would have been lost pursuant to the proposed Acquisition.

Based in San Diego, California, Quidel develops, manufactures, and markets point-of-care diagnostic testing solutions globally. The company has expertise with immunoassay testing and currently focuses on infectious diseases, women’s and general health, and gastrointestinal diseases. The acquisition of Alere’s point-of-care cardiac marker testing business will complement Quidel’s portfolio of rapid diagnostic testing solutions. Moreover, Quidel’s chairman was co-inventor of Alere’s point-of-care cardiac marker testing system, providing Quidel with additional understanding and background of the divestiture business.

The parties must accomplish the divestitures no later than thirty days after the consummation of the Proposed Acquisition. If the Commission determines that either Siemens or Quidel is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires the parties to unwind the sale of rights to Siemens and/or Quidel and then divest the products to a Commission-approved acquirer(s) within six months of the date the Order becomes final.

The Commission has agreed to appoint a Monitor to ensure that Abbott and Alere 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 Siemens and Quidel. The proposed Order further allows the Commission to appoint a trustee in the event the parties 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.

Donald S. Clark,
Secretary.

[FR Doc. 2017–21290 Filed 10–3–17; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 162 3128]

Moonlight Slumber, LLC; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

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 October 30, 2017.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write: “In the Matter of Moonlight Slumber, LLC, File No. 1623128” on your comment, and file your comment online at <https://ftcpublic.commentworks.com/ftc/moonlightslumberconsent> by following the instructions on the web-based form. If you prefer to file your comment on paper, write “In the Matter of Moonlight Slumber, LLC, File No. 1623128” 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.

FOR FURTHER INFORMATION CONTACT: Amanda Kostner (202–326–2880) and Jock Chung (202–326–2984), Bureau of Consumer Protection, 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 Home Page (for September 28, 2017), on the World Wide Web, at <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 October 30, 2017. Write "In the Matter of Moonlight Slumber, LLC, File No. 1623128" 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 public Commission Web site, at <https://www.ftc.gov/policy/public-comments>.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublishcommentworks.com/ftc/moonlightslumberconsent> by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov/#/home>, you also may file a comment through that Web site.

If you prefer to file your comment on paper, write "In the Matter of Moonlight Slumber, LLC, File No. 1623128" 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 FTC Web site at <https://www.ftc.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 that 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 Web site—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC Web site, 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 Web site 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 October 30, 2017. 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 ("FTC" or "Commission") has accepted, subject to final approval, an agreement

containing a consent order from Moonlight Slumber, LLC ("respondent").

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves the deceptive environmental and health claims respondent made regarding its baby mattresses. According to the FTC complaint, respondent made unsubstantiated representations that its mattresses are organic, natural, or plant-based and that its mattresses will not emit any substance, including volatile organic compounds, or off gas; claimed that testing proved that its mattresses do not emit volatile organic compounds; and represented that its mattresses have been certified by Green Safety Shield, yet failed to disclose that it has a material connection to the Green Safety Shield seal. Consumers likely interpret such seals as a claim that an independent third party certified the product. The complaint alleges that all of these claims are deceptive in violation of Section 5(a) of the FTC Act.

The proposed consent order contains five provisions designed to prevent respondent from engaging in similar acts and practices in the future. Part I prohibits misleading representations regarding whether any mattress, blanket, pillow, pad, foam-containing product, or sleep-related product is organic, natural, or plant-based; regarding the emissions from such product; and regarding the general environmental and health benefits of such product. The order requires respondent to possess competent and reliable evidence, including scientific evidence when appropriate, to substantiate these representations.

Part II prohibits misleading representations regarding emissions-free and VOC-free claims. The order requires competent and reliable scientific evidence to substantiate that a product does not emit more than a trace level of emissions of the substance about which the claim is made. The order defines "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. Consistent with the Green Guides, the order defines “trace level of emissions” for claims for a substance to mean that (1) emissions of the substance do not result in inhalation concentrations of that substance higher than background levels in the typical residential home; (2) emissions of the substance do not cause material harm that consumers typically associate with that substance, including harm to the environment or human health; and (3) the substance has not been added intentionally to the covered product.

Part III prohibits respondent from misrepresenting the results of any tests or studies, or from misrepresenting that any product benefit is scientifically or clinically proven. Parts IV and V prohibit respondent from misrepresenting certifications or failing to adequately disclose a material connection to a party making a representation, e.g., an endorser.

Parts VI through X are reporting and compliance provisions. Part VI 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 VII requires that respondent submit compliance reports to the FTC within ninety (90) days of the order’s issuance and submit additional reports when certain events occur. Part VIII requires that respondent create and retain certain records for five (5) years. Part IX provides for the FTC’s continued compliance monitoring of respondent’s activity during the order’s effective dates. Part X is a provision “sunsetting” the order after twenty (20) years, with certain exceptions.

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. 2017–21289 Filed 10–3–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10110]

Agency Information Collection Activities: Submission for OMB Review; 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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by November 3, 2017.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 OR Email: OIRA_submission@omb.eop.gov.

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’ Web site address at Web site 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 Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Manufacturer Submission of Average Sales Prices (ASP) Data for Medicare Part B Drugs; *Use:* In accordance with Section 1847A of the Social Security Act (the Act), Medicare Part B covered drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price (ASP) of the drug or biological, beginning in Calendar Year (CY) 2005. The ASP data reporting requirements are specified in Section 1927 of the Act. The reported ASP data are used to establish the Medicare payment amounts. *Form Number:* CMS–10110 (OMB control number: 0938–0921); *Frequency:* Quarterly; *Affected Public:* Business or other For-profits; *Number of Respondents:* 180; *Total Annual Responses:* 720; *Total Annual Hours:* 9360. (For policy questions regarding this collection contact Felicia Eggleston at 410–786–9287.)

Dated: September 28, 2017.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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