• CSU retail sales or shipments, especially information about the type of CSUs sold and the number of units sold in recent years;
• the number of CSUs in use;
• studies, tests, or descriptions of technologies or design changes that address tip-over injuries and estimates of costs associated with those features, including manufacturing costs and wholesale prices;
• the expected impact of technologies or design changes that address tip-over injuries on manufacturing costs or wholesale prices;
• the potential impact of design changes to address CSU stability on consumer utility; and
• information about whether any stability requirements for CSUs in ether a voluntary standard or potential mandatory rule could have a disparate impact on small entities, such as small manufacturers or importers.

In addition, the Commission invites interested parties to submit any existing standards, or portions of them, for consideration as a consumer product safety standard. The Commission also invites interested persons to submit a statement of intention to modify or develop a voluntary consumer product safety standard addressing the risk of injury associated with CSU tip overs, including a description of the plan to develop or modify such a standard.

Please submit comments in accordance with the instructions in the **ADDRESSES** section at the beginning of this ANPR.

Alberta E. Mills,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 2017–25779 Filed 11–29–17; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 40

[Docket No. RM16–22–000]

Coordination of Protection Systems for Performance During Faults and Specific Training for Personnel Reliability Standards

Correction

Proposed Rule document 2017–25586 beginning on page 56186 was incorrectly published in the issue of Tuesday, November 28, 2017.

[FR Doc. C1–2017–25586 Filed 11–29–17; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA–2017–N–6529]

The Food and Drug Administration's Approach To Evaluating Nicotine Replacement Therapies; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public hearing on FDA's approach to evaluating the safety and efficacy of nicotine replacement therapy (NRT) products, including how they should be used and labeled.

DATES: The public hearing will be held on Friday, January 26, 2018, from 9 a.m. to 5 p.m. The public hearing may be extended or may end early depending on the level of public participation. Persons seeking to attend or to present at the public hearing must register by Tuesday, January 2, 2018. Section II provides attendance and registration information. Electronic or written comments will be accepted after the public hearing until Thursday, February 15, 2018.

ADDRESSES: The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room A, Silver Spring, MD 20993–0002. Entrance for public hearing participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 15, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of February 15, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified as confidential if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–6529 for ''FDA's Approach to Evaluating Nicotine Replacement Therapies''; Public Hearing; Request for Comments. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential

with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the received electronic and written/paper comments, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Allison Hoffman, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 1314, Silver Spring, MD 20993, 301–796–9203, *OMPTFeedback@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

A majority (roughly 70%) of adult smokers in the United States report that they want to quit, and nearly half of them make a quit attempt each year. Many of those quit attempts involve the use of NRT products, which are designed to help people quit smoking by supplying controlled amounts of nicotine to ease their withdrawal symptoms. FDA has approved two types of prescription [1] NRT products—a nicotine nasal spray and nicotine inhaler—and three types of over-the-counter (OTC) NRT products—a nicotine gum, transdermal nicotine patch, and nicotine lozenge (see Appendix A). Most of these products have been approved for over 20 years.[2] The use of approved prescription and OTC NRT products is generally considered to double the likelihood of a successful quit attempt, although there is variation in efficacy among the types of products.

Although the formulations and routes of administration of currently approved NRT products have remained relatively unchanged for decades, there have been developments in research regarding NRT products and corresponding changes in the regulatory landscape. For example, in 2013, FDA recommended changing the statements on concomitant use and duration of use in the labeling for OTC NRT products because evidence gathered since 1984—the year the first NRT product was approved—suggested that the statements were no longer necessary to ensure the safe use of OTC NRT products for smoking cessation.[3] Specifically, the Agency recommended that the statement in the labeling for OTC NRT products warning consumers that they should not use an NRT product if they are still smoking, or using any other product that contains nicotine—including another NRT—be removed. FDA also recommended that the directions in the labeling for OTC NRT products be modified to remove the statement advising consumers to stop using the product at the end of the labeled duration of use. Instead of this statement, FDA recommended that consumers be advised to talk to their health care provider if they feel the need to use the product for longer than the labeled duration of use to keep from smoking. To facilitate these labeling changes, FDA invited the submission of supplemental new drug applications (labeling supplements).

On July 28, 2017, the FDA announced a new comprehensive plan that places nicotine, and the issue of addiction, at the center of the Agency's tobacco regulation efforts. This plan will serve as a multi-year roadmap to better protect children and significantly reduce tobacco-related disease and death in the United States. One of the first actions of this comprehensive approach will be an advanced notice of proposed rulemaking (ANPRM) to seek input on the potential impacts of reducing nicotine levels in cigarettes to minimally or non-addictive levels. A key piece of the FDA's comprehensive plan is a recognition that nicotine—while highly addictive—is delivered through products that represent a continuum of risk and is most harmful when delivered through combustible tobacco products. Accordingly, the Agency is committed to increasing access to and use of nicotine replacement therapy, which could help more smokers quit. Therefore, the Agency is seeking public input on its approach to evaluating the safety and efficacy of NRT products.

As a part of its mission to protect and promote public health, FDA is responsible for ensuring that approved drugs, including NRT products, are safe and effective.[4] For FDA to approve a new drug, it must find that the applicant has submitted ''substantial evidence'' of effectiveness based on adequate and well-controlled studies [5] and that the drug is safe for use under the conditions set forth in the labeling.[6] Generally, the safety of a product is assessed by determining whether its benefits outweigh its risks. The benefit–risk assessment takes into account the extensive evidence of safety and effectiveness submitted by a sponsor in a marketing application as well as many other factors.[7]

II. Purpose and Scope of the Public Hearing

To enable a thorough assessment of its approach for evaluating the safety and efficacy NRT products and how they should be used and labeled, FDA is holding a public hearing to receive information and comments from a broad group of stakeholders, including the public health community, researchers, health care professionals, manufacturers, interested industry and professional organizations, and the public, on the appropriate study designs and methods for evaluating the safety and efficacy of OTC NRT drug products. FDA is also seeking input on the warnings and directions sections of the Drug Facts labeling (among other

[1] Non-nicotine prescription medications are also available to aid in smoking cessation, but are beyond the scope of this document.

[2] Only the lozenge formulation has been approved for less than 20 years; it was approved in 2002.

[3] See the **Federal Register**, available at *https://www.federalregister.gov/documents/2013/04/02/2013-07528/modifications-to-labeling-of-nicotine-replacement-therapy-products-for-over-the-counter-human-use*. Recommendations also included other language revisions that were not related to dosing or duration.

[4] Section 1003(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 393(b).

[5] Section 505(d) of the FD&C Act; 21 U.S.C. 355(d).

[6] 21 U.S.C. 355(d). FDA also noted in the preamble to the final rule on new drug approvals (NDA final rule) that the new drug approval process and the supplemental application requirements ''are intended to ensure that the drug is safe, that its benefits outweigh its risks, and that it is effective.'' See 50 FR 7452, 7469 (February. 22, 1985).

[7] See FDA's *Structured Approach to Benefit–Risk Assessment in Drug Regulatory Decision-Making, Draft PDUFA V Implementation Plan*—February 2013, Fiscal Years 2013–2017, available at *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf*.

aspects) for approved OTC NRT products, specifically regarding the possible impact of current warnings on likelihood of use. The Agency has determined that a public hearing is the most appropriate way to ensure public engagement on these important public health issues. FDA believes it is critical to obtain input across the research and medical fields, the tobacco and pharmaceutical industries, and among public health stakeholders regarding how evolving science could influence FDA's approach to evaluating the safety and effectiveness of NRT products.

Questions for Commenters To Address

Although FDA welcomes all feedback on any public health, scientific, regulatory or legal considerations relating to NRT products and their use in tobacco use cessation, we encourage commenters to consider the following questions as they prepare their comments or statements. Responses to questions should include supporting scientific justification.

1. Might there be ways to improve upon the currently available delivery systems to yield new OTC NRT products that might be more effective? If so, what evidence would be needed to support such changes, and how should they be evaluated?

2. Are there additional indications or regimens for OTC NRT products that could be explored? Concepts to consider could include relapse prevention, craving reduction, maintenance, reduce to quit, use of short- and long-acting products in combination, or cessation of non-cigarette tobacco products. What evidence would be needed to support each indication or regimen?

3. What data would be required to demonstrate health benefits of reduction in consumption of combustible tobacco products?

4. Are there OTC NRT products that could be studied for use in combination that might result in reduced tobacco-related health impacts? What evidence would be needed to support the safety and efficacy of these products when used in combination?

5. Is there other information that could be added to labeling for currently approved or new dosage forms of OTC NRT products that would maximize their ability to be used to support smoking cessation? Please consider the various sections of the Drug Facts labeling, including the Uses, Warnings, and Directions sections.

6. Generally, the labeling of OTC NRT products contains a dosing schedule based on duration of use, and FDA has recommended the labeling on OTC NRT products be modified to include the following: ''If you feel you need to use [the NRT product] for a longer period to keep from smoking, talk to your health care provider.'' What is the impact of longer term NRT treatment? What is the impact on likelihood of cessation or relapse prevention? What data would support an affirmative recommendation to use approved OTC NRT products for durations that exceed those currently included in the Drug Facts labeling of approved OTC NRT products, or would support a chronic or maintenance drug treatment indication for such products?

Registration and Requests for Oral Presentations: The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. If you wish to attend (either in person or by webcast (see *Streaming Webcast of the Public Hearing*)) and/or present at the hearing, please register for the hearing and/or make a request for oral presentations or comments by email to *OMPTfeedback@fda.hhs.gov* by Tuesday, January 2, 2018. The email should contain complete contact information for each attendee (*i.e.,* name, title, affiliation, address, email address, and telephone number). For those wishing to present at the hearing, the email should also include a presentation title. Those without email access can register by contacting Allison Hoffman at 301–796–9203 by Tuesday, January 2, 2018 (see **FOR FURTHER INFORMATION CONTACT**).

FDA will try to accommodate all persons who wish to make a presentation. Individuals wishing to present should identify the number of the specific question, or questions, they wish to address. This will help FDA organize the presentations. Individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. FDA will notify registered presenters of their scheduled presentation times. The time allotted for each presentation will depend on the number of individuals who wish to speak. Presenters are encouraged to submit an electronic copy of their presentation to *OMPTfeedback@fda.hhs.gov* on or before Friday, January 19, 2018. Persons registered to make an oral presentation are encouraged to arrive at the hearing room early and check in at the onsite registration table to confirm their designated presentation time. An agenda for the hearing and any other background materials will be made available 5 days before the hearing at *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm580561.htm.*

If you need special accommodations because of a disability, please contact *OMPTFeedback@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) no later than Tuesday, January 2, 2018, at 12 noon Eastern Time.

Streaming Webcast of the Public Hearing: For those unable to attend in person, FDA will provide a live webcast of the hearing. To join the hearing via the webcast, please go to *https://collaboration.fda.gov/part15nicotine.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**).

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with 21 CFR part 15. The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner, the Center for Drug Evaluation and Research, and the Center for Tobacco Products. Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members can pose questions; they can question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C). Under § 10.205, representatives of the media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see *Transcripts*). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

IV. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal**

Register, but Web sites are subject to change over time.

1. Babb S, Malarcher A, Schauer G, Asman K, and Jamal A. 2017. Quitting Smoking Among Adults—United States, 2000–2015. *Morbidity and Mortality Weekly Report* 65:1457–1464.
2. Etter J-F and Stapleton JA. 2006. Nicotine Replacement Therapy for Long-Term Smoking Cessation: A Meta-Analysis. *Tobacco Control* 15:280–285.
3. Silagy C, Mant D, Fowler G, and Lodge M. 1994. Meta-Analysis on Efficacy of Nicotine Replacement Therapies in Smoking Cessation. *Lancet* 343:139–142.

Appendix A: Summary of FDA-Approved Active New Drug Applications (NDAs) of Nicotine Replacement Therapies (September 18, 2017)

Product name (NDA #; holder)	OTC or Rx (date approved; date Rx→OTC)	Route (doses)	Indication	Labeled treatment duration and schedule
Nicorette gum (nicotine polacrilex) (NDA 018612 for 2 mg, NDA 020066 for 4 mg; GSK).	Approved as prescription on 1/13/84 for 2 mg; 6/8/92 for 4 mg; Rx→OTC for both on 2/9/16.	Oral (2, 4 mg gum).	Reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking (under Directions: If you are under 18 years of age ask a doctor before use).	12 weeks: • Wk 1–6: 1 per 1–2 hr. • Wk 7–9: 1 per 2–4 hr. • Wk 10–12: 1 per 4–8 hr. If smoke 1st cigarette within 30 min of waking up, use 4 mg; if more than 30 min, use 2 mg.
NicoDerm CQ (nicotine) (NDA 020165; GSK, Sanofi Aventis).	Approved as prescription on 11/7/91; Rx→OTC on 8/2/96.	Patch (7, 14, 21 mg).	Same use as above	10 weeks and 8 weeks: If >10 cigarettes/day: • Wk 1–6: one 21 mg/day. • Wk 7–8: one 14 mg/day. • Wk 9–10: one 7 mg/day. If ≤10 cigarettes/day: • Wk 1–6: one 14 mg/day. • Wk 7–8: one 7 mg/day.
Habitrol (nicotine) (NDA 020076; Ciba-Geigy, Novartis, Dr. Reddy's).	Approved as prescription on 11/27/91; Rx→OTC on 11/12/99.	Patch (7, 14, 21 mg).	Same use as above	8 weeks: If >10 cigarettes/day: • Wk 1–4: one 21 mg/day. • Wk 5–6: one 14 mg/day. • Wk 7–8: one 7 mg/day. If ≤10 cigarettes/day: • Wk 1–6: one 14 mg/day. • Wk 7–8: one 7 mg/day.
Nicotrol NS (nicotine) (NDA 020385; Pfizer).	Prescription (3/22/96; N/A) ...	Nasal spray	• Indicated as an aid to smoking cessation for the relief of nicotine withdrawal symptoms. • Should be used as a part of a comprehensive behavioral smoking cessation program.	The label does not specify the recommended duration of treatment, but notes the following in the Indications and Usage section: The safety and efficacy of the continued use of Nicotrol NS for periods longer than 6 months have not been adequately studied and such use is not recommended.
Nicotrol Inhaler (nicotine) (NDA 020714; Pharmacia and Upjohn).	Prescription (5/2/97; N/A)	Inhalant	• Indicated as an aid to smoking cessation for the relief of nicotine withdrawal symptoms. • Recommended for use as part of a comprehensive behavioral smoking cessation program.	The recommended duration of treatment is 3 months, after which patients may be weaned from the inhaler by gradual reduction of the daily dose over the following 6 to 12 weeks. The safety and efficacy of the continued use of Nicotrol Inhaler for periods longer than 6 months have not been studied and such use is not recommended.

Product name (NDA #; holder)	OTC or Rx (date approved; date Rx→OTC)	Route (doses)	Indication	Labeled treatment duration and schedule
Commit lozenge (nicotine polacrilex) (NDA 021330; GSK).	OTC (10/3/02; N/A)	Oral (2, 4 mg) ...	Reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking (under Directions: If you are under 18 years of age ask a doctor before use).	12 weeks: • Wk 1–6: 1 per 1–2 hr. • Wk 7–9: 1 per 2–4 hr. • Wk 10–12: 1 per 4–8 hr. If smoke 1st cigarette within 30 min of waking up, use 4 mg; if more than 30 min, use 2 mg.
Nicorette mini lozenge (nicotine polacrilex) (NDA 022366; GSK).	OTC (5/18/09; N/A)	Oral (2, 4 mg) ...	Same use as above	12 weeks; same schedule as Commit lozenge.

Dated: November 22, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–25671 Filed 11–29–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2017–N–4919]

Medical Devices; Exemption From Premarket Notification: Class II Devices; Surgical Apparel; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing its intention to exempt certain subtypes of surgical apparel from premarket notification requirements, subject to conditions and limitations. FDA intends to limit the proposed exemption to single-use, disposable respiratory protective devices (RPD) used in a healthcare setting and worn by healthcare personnel during procedures to protect both the patient and the healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. These devices, commonly referred to as N95 filtering facepiece respirators (FFRs) and surgical N95 respirators (herein collectively referred to as N95s) are currently regulated by FDA under product code MSH. All other class II devices classified under FDA's surgical apparel classification regulation would continue to be subject to premarket notification requirements. FDA is publishing this document to obtain comments regarding this proposed exemption, in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments by January 29, 2018.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 29, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 29, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–4919 for ''Medical Devices; Exemption From Premarket Notification: Class II Devices; Surgical Apparel; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and