PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

■ 1. The authority citation for Part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

■ 2. In § 72.214, Certificate of Compliance 1025 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1025.

Initial Certificate Effective Date: April 10, 2000.

Amendment Number 1 Effective Date: November 13, 2001.

Amendment Number 2 Effective Date: May 29, 2002.

Amendment Number 3 Effective Date: October 1, 2003.

Amendment Number 4 Effective Date: October 27, 2004.

Amendment Number 5 Effective Date: July 24, 2007.

Amendment Number 6 Effective Date: October 4, 2010.

Amendment Number 7 Effective Date: March 4, 2019.

Amendment Number 8 Effective Date: March 4, 2019.

SAR Submitted by: NAC International, Inc.

SAR Title: Final Safety Analysis Report for the NAC Multi-Purpose Canister System (NAC–MPC System).

Docket Number: 72–1025.

Certificate Expiration Date: April 10, 2020.

Model Number: NAC–MPC.

* * * * *

Dated at Rockville, Maryland, this 4th day of December, 2018.

For the Nuclear Regulatory Commission.

Margaret M. Doane,

Executive Director for Operations.

[FR Doc. 2018–27286 Filed 12–17–18; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA–2018–N–3952]

Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies; New Date for Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of new date for public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a new date for the public hearing to discuss its efforts to eliminate youth electronic cigarette (e-cigarette) use as well as other tobacco product use, with a focus on the potential role of drug therapies to support youth e-cigarette cessation and the issues impacting the development of such therapies. FDA is also extending the comment period.

DATES: The public hearing will be held on January 18, 2019, 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 present at the public hearing must register by January 8, 2019. Persons seeking to speak at the public hearing must register by January 15, 2019. Persons seeking to attend, but not present at, the public hearing must register by January 15, 2019. Section III provides attendance and registration information. Electronic or written comments will be accepted after the public hearing until February 1, 2019.

ADDRESSES: The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), 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 1, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 1, 2019. 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–2018–N–3952 for ''Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug 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 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 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: Theresa Wells, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 1202, Silver Spring, MD 20993, 703–380–3900, *Theresa.wells@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Nearly all tobacco product use begins during youth and young adulthood (Ref. 1). While the current use of any tobacco product among U.S. middle and high school students has decreased from 2011 to 2017, there has been an alarming increase in e-cigarette use over this time. In fact, since 2014, e-cigarettes [1] have been the most commonly used tobacco products among youth, used by 1.73 million (11.7 percent) high school students and 390,000 (3.3 percent) middle school students in 2017 (Ref. 2). Youth e-cigarette use raises a number of health concerns including risk of addiction to nicotine early on in life, potential harm to the developing adolescent brain, and exposure to chemicals including carbonyl compounds and volatile organic compounds known to have adverse health effects; the full range of possible health effects is not yet completely understood (Ref. 3).

On April 24, 2018, FDA announced its Youth Tobacco Prevention Plan. This plan focuses on three key strategies: Prevention of youth access to tobacco products, curbing the marketing of tobacco products aimed at youth, and educating teens about the dangers of using any tobacco products.[2] FDA recently launched an expansion of its ''The Real Cost'' campaign to educate youth on the dangers of e-cigarette use [3] and increased enforcement actions to address this critically important public health concern.[4]

In addition to the prevention of initiation, which will be the cornerstone of any successful effort to curb youth e-cigarette use, FDA is also exploring additional approaches to address youth e-cigarette use. One such approach may be the development of drug therapies, as part of multimodal treatment strategies, including behavioral interventions, to support tobacco product cessation. To date, research on youth tobacco product cessation has been limited and focused on smoking (*i.e.,* combustible products) cessation. One recent review found a paucity of data on either behavioral or drug therapies for smoking cessation in young people (age less than 20 years) and concluded that ''there continues to be a need for well-designed, adequately powered, randomized controlled trials of interventions for this population of smokers'' (Ref. 4). FDA is not aware of any research examining either drug or behavioral interventions for the cessation of youth or adult e-cigarette use. In contrast, there is a large body of research on adult smoking cessation, and multiple drugs for smoking cessation are approved for the adult population, including a variety of prescription and over-the-counter nicotine replacement therapy (NRT) products, as well as the prescription drugs varenicline and bupropion hydrochloride sustained release (see Appendix A).

[1] An e-cigarette is one type of electronic nicotine delivery system, which also includes e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes. See *https://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm456610.htm* and Ref. 2.

[2] *https://www.fda.gov/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm608433.htm.*

[3] *https://www.fda.gov/tobaccoproducts/publichealtheducation/publiceducationcampaigns/therealcostcampaign/default.htm.*

[4] *https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620788.htm.*

II. Purpose and Scope of the Public Hearing

FDA is holding a public hearing to obtain the public's perspectives on the potential role drug therapies may play in the broader effort to eliminate youth e-cigarette and other tobacco product use, as well as the appropriate methods and study designs for evaluating youth e-cigarette cessation therapies and the safety and efficacy of such therapies. The Agency has determined that a public hearing is the most appropriate way to ensure public engagement on this issue, which is of great importance to the public health. FDA believes it is critical to obtain input across the medical and research fields, the pharmaceutical and tobacco industries, and among public health stakeholders (including adolescents) regarding approaches to eliminate youth e-cigarette and other tobacco product use, including exploring whether there is a need for drug therapies to support youth e-cigarette cessation, and if so, how FDA can support the development of such therapies.

Questions for Commenters to Address: Considering the broad range of activities focused on this public health issue, FDA is interested in the public's view on approaches to eliminating e-cigarette and other tobacco product use among youth. Although FDA welcomes all feedback on any public health, scientific, regulatory, or legal considerations relating to this topic, we particularly encourage commenters to consider the following questions as they prepare their comments or statements. Responses to questions should include supporting scientific justification.

1. FDA notes that the factors driving e-cigarette use among youth likely differ from those in the adult population. How might such differences impact the need for, or use of, drug therapies for e-cigarette cessation among youth?

2. FDA is interested in whether there is a population of youth e-cigarette users who would be likely to benefit from the use of drug therapies for e-cigarette cessation. What age groups (older adolescent vs. younger adolescent), patterns in tobacco use (duration and frequency of use), and clinical features (level of addiction, presence/absence of

comorbidities including psychiatric disease) might characterize this population? What types of products (NRT vs. non-NRT; prescription vs. over-the-counter) might be useful?

3. Describe the scientific, clinical, and societal factors that could either encourage or impede the conduct of clinical trials designed to evaluate drugs intended for youth e-cigarette cessation. What approaches could be used to encourage research and overcome barriers to research?

4. What methods and study designs are appropriate for assessing drug therapies for youth e-cigarette cessation? What are the appropriate control groups? What are the most informative endpoints and the best assessment tools to evaluate these endpoints?

5. Acknowledging that to date research has been limited, are there data available from the adult experience with smoking cessation that could potentially be leveraged in the effort to develop drug therapies for youth e-cigarette cessation? Have any drug therapies demonstrated potential to help adults discontinue e-cigarette use? Are there differences between adolescents and adults that impact the ability to extrapolate efficacy findings from the adult population to the adolescent population? Could existing NRT products be useful for youth e-cigarette cessation?

6. While this hearing is focused on the topic of e-cigarette use among youth, as e-cigarettes are currently the most commonly used form of tobacco in this population, FDA also welcomes comments regarding the potential need for drug therapies to support cessation of other tobacco products, including combustible products (*i.e.,* cigarettes or cigars) and smokeless tobacco products, among youth and the issues impacting the development of such therapies.

III. Participating in the Public Hearing

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. For those interested in presenting at the meeting with a formal oral presentation, please register by January 8, 2019, at *https://www.eventbrite.com/e/fda-pediatric-tobacco-cessation-part-15-public-hearing-tickets-50167147288.* For those interested in participating as a speaker during the open public hearing, please register by January 15, 2019, at *https://www.eventbrite.com/e/fda-pediatric-tobacco-cessation-part-15-public-hearing-tickets-50167147288.* If you wish to attend either in person or by webcast (see *Streaming Webcast of the Public Hearing*), please register for the hearing by January 15, 2019, at *https://www.eventbrite.com/e/fda-pediatric-tobacco-cessation-part-15-public-hearing-tickets-50167147288.* Those without internet or email access can register and/or request to participate as an open public hearing speaker or a formal presenter by contacting Theresa Wells by the above dates (see **FOR FURTHER INFORMATION CONTACT**).

FDA will try to accommodate all persons who wish to make a presentation. Formal oral presenters may use an accompanying slide deck, while those participating in the open public hearing will have less allotted time than formal oral presenters and will deliver oral testimony only (no accompanying slide deck). 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. Individual organizations are limited to a single presentation slot. 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. Registered presenters making a formal oral presentation are encouraged to submit an electronic copy of their presentation (PowerPoint or PDF) to *OMPTFeedback@fda.hhs.gov* with the subject line ''Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies'' on or before January 11, 2019. Persons registered to present are encouraged to arrive at the hearing room early and check in at the onsite registration table to confirm their designated presentation time. Actual presentation times, however, may vary based on how the meeting progresses in real 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/ucm620744.htm.*

If you need special accommodations because of a disability, please contact Theresa Wells (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the hearing.

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/ptc120518.*

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**).

IV. 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 part 15 (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) (21 CFR 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 21 CFR 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).

V. References

The following references marked with an asterisk (*) are on display at 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 also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1.* U.S. Department of Health and Human Services (2014). ''The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General, 2014.'' Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. (Available at: *https://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html.*)

2.* Wang T.W., A. Gentzke, S. Sharapova, et al. (2018). ''Tobacco Product Use Among Middle and High School Students—United States, 2011–2017.'' *Morbidity and Mortality Weekly Report (MMWR)* 67:629–633. (Available at *https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a3.htm.*)

3.* U.S. Department of Health and Human Services (2016). ''E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General.'' Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. (Available at: *https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf.)*

4. Fanshawe T.R., W. Halliwell, N. Lindson, et al. (2017). ''Tobacco Cessation Interventions for Young People.'' *Cochrane Database of Systematic Reviews,* Rev.11:CD003289. (Available at *https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003289.pub6/epdf/full.*)

BILLING CODE 4164–01–P

Appendix A: Summary of FDA-Approved Active NDAs of NRTs and non-NRTs Indicated for Smoking Cessation (October 5, 2018)

Product Name (NDA #; holder)	OTC or Rx (Date approved; Date Rx→OTC)	Route (Doses)	Indication	Adult Treatment Duration and Schedule	Pediatric Labeling
NRT Therapies					
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 2/9/96.	Oral (2, 4 mg gum)	Reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking.	12 weeks (for longer use, talk to health care provider): • 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.	If you are under 18 years of age ask a doctor before use.
NicoDerm CQ (nicotine) (NDA 020165; Sanofi Aventis)	Approved as prescription on 11/7/91; Rx→OTC on 8/2/96.	Patch (7, 14, 21 mg)	Same as above	10 weeks and 8 weeks (for longer use, talk to health care provider): 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	Same as above
Habitrol (nicotine) (NDA 020076; Dr. Reddy's)	Approved as prescription on 11/27/91; Rx→OTC on 11/12/99.	Patch (7, 14, 21 mg)	Same as above	8 weeks (for longer use, talk to health care provider): 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	Same as above

Product Name (NDA #; holder)	OTC or Rx (Date approved; Date Rx→OTC)	Route (Doses)	Indication	Adult Treatment Duration and Schedule	Pediatric Labeling
Nicotrol NS (nicotine) (NDA 020385; Pfizer)	Prescription (3/22/96; N/A)	Nasal spray (50 microliter spray delivering 0.5 mg)	• 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	2 sprays (one per nostril) = 1 dose • Starting dose: 1-2 doses/hour • Maximum doses/hour: 5 • Maximum doses/day: 40 Maximum recommended duration of treatment: 3 months 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.	Under Pediatric Use: Not recommended for use in the pediatric population because its safety and effectiveness in children and adolescents who smoke have not been evaluated.
Nicotrol Inhaler (nicotine) (NDA 020714; Pharmacia and Upjohn)	Prescription (5/2/97; N/A)	Inhalant (10 mg cartridge; 4 mg delivered)	• 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.	Safety and effectiveness in pediatric and adolescent patients below the age of 18 years have not been established for any nicotine replacement product. However, no specific medical risk is known or expected in nicotine dependent adolescents. NICOTROL Inhaler should be used for the treatment of tobacco dependence in the older adolescent only if the potential benefit justifies the potential risk.
Nicorette lozenge (nicotine polacrilex) (NDA 021330; GSK)	OTC (10/31/02; N/A)	Oral (2, 4 mg)	Reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking.	12 weeks (for longer use, talk to health care provider): • 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.	If you are under 18 years of age ask a doctor before use. No studies have been done to show if this product will work for you.
Nicorette mini lozenge (nicotine polacrilex) (NDA 022360; GSK)	OTC (5/18/09; N/A)	Oral (2, 4 mg)	Same as above	Same as above	Same as above
Non-NRT Therapies					
Zyban (bupropion hydrochloride sustained release) (NDA 020711; GSK)	Prescription (5/14/97; N/A)	Oral (150 mg)	• Indicated as an aid to smoking cessation treatment	7-12 weeks • Start at one 150-mg tablet per day for 3 days • Can increase to 300 mg per day given as one 150-mg tablet twice each day, with 8 hours between Patient may benefit from ongoing treatment.	Safety and effectiveness in the pediatric population have not been established. Boxed Warning for suicidality in children, adolescents, and young adults in setting of bupropion use as an antidepressant.

Dated: December 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–27352 Filed 12–17–18; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–132881–17]

RIN 1545–BO30

Regulations Reducing Burden Under FATCA and Chapter 3

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations eliminating withholding on payments of gross proceeds, deferring withholding on foreign passthru payments, eliminating withholding on certain insurance premiums, and clarifying the definition of investment entity. This notice of proposed rulemaking also includes guidance concerning certain due diligence requirements of withholding agents and guidance on refunds and credits of amounts withheld.

DATES: Written or electronic comments and requests for a public hearing must be received by February 19, 2019.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–132881–17), Internal Revenue Service, Room 5203, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may also be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–132881–17), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224; or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–132881–17).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, John Sweeney, Nancy Lee, or Subin Seth, (202) 317–6942; concerning submissions of comments and/or requests for a public hearing, Regina Johnson, (202) 317–6901 (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) under chapter 4 (sections 1471 through 1474) commonly known as the Foreign Account Tax Compliance Act (FATCA). This document also contains amendments to the Income Tax Regulations (26 CFR part 1) under sections 1441 and 1461.

On January 28, 2013, the Department of the Treasury (Treasury Department) and the IRS published final regulations under chapter 4 in the **Federal Register** (TD 9610, 78 FR 5873), and on September 10, 2013, corrections to the final regulations were published in the **Federal Register** (78 FR 55202). The regulations in TD 9610 and the corrections thereto are collectively referred to in this preamble as the 2013 final chapter 4 regulations. On March 6, 2014, the Treasury Department and the IRS published temporary regulations under chapter 4 (TD 9657, 79 FR 12812) that clarify and modify certain provisions of the 2013 final chapter 4 regulations, and corrections to the temporary regulations were published in the **Federal Register** on July 1, 2014, and November 18, 2014 (79 FR 37175 and 78 FR 68619, respectively). The regulations in TD 9657 and the corrections thereto are referred to in this preamble as the 2014 temporary chapter 4 regulations. A notice of proposed rulemaking cross-referencing the 2014 temporary chapter 4 regulations was published in the **Federal Register** on March 6, 2014 (79 FR 12868).

On March 6, 2014, the Treasury Department and the IRS published temporary regulations under chapters 3 and 61 in the **Federal Register** (TD 9658, 79 FR 12726) to coordinate with the regulations under chapter 4, and corrections to those temporary regulations were published in the **Federal Register** (79 FR 37181) on July 1, 2014. Collectively, the regulations in TD 9657 and the corrections thereto are referred to in this preamble as the 2014 temporary coordination regulations. A notice of proposed rulemaking cross-referencing the 2014 temporary coordination regulations was published in the **Federal Register** on March 6, 2014 (79 FR 12880).

On January 6, 2017, the Treasury Department and the IRS published final and temporary regulations under chapter 4 in the **Federal Register** (TD 9809, 82 FR 2124), and corrections to those final regulations were published on June 30, 2017 in the **Federal Register** (82 FR 27928). Collectively, the regulations in TD 9809 and the corrections thereto are referred to in this preamble as the 2017 chapter 4 regulations. A notice of proposed rulemaking cross-referencing the temporary regulations in TD 9809 and proposing regulations under chapter 4 relating to verification requirements for certain entities was published in the **Federal Register** on January 6, 2017 (82 FR 1629). Also on January 6, 2017, the Treasury Department and the IRS published final and temporary regulations under chapters 3 and 61 in the **Federal Register** (TD 9808, 82 FR 2046), and corrections to those final regulations were published on June 30, 2017 in the **Federal Register** (82 FR 29719). Collectively, the regulations in TD 9808 and the corrections thereto are referred to in this preamble as the 2017 coordination regulations. A notice of proposed rulemaking cross-referencing the temporary regulations in TD 9808 was published in the **Federal Register** on January 6, 2017 (82 FR 1645).

Pursuant to Executive Order 13777, Presidential Executive Order on Enforcing the Regulatory Reform Agenda (82 FR 9339), the Treasury Department is responsible for conducting a broad review of existing regulations. In a Request for Information published on June 14, 2017 (82 FR 27217), the Treasury Department invited public comment concerning regulations that should be modified or eliminated in order to reduce unnecessary burdens. In addition, in Notice 2017–28 (2017–19 I.R.B. 1235), the Treasury Department and the IRS invited public comment on recommendations for the 2017–2018 Priority Guidance Plan for tax guidance, including recommendations relating to Executive Order 13777. In response to the invitations for comments in the Request for Information and Notice 2017–28, the Treasury Department and the IRS received comments suggesting modifications to the regulations under chapters 3 and 4. See also Executive Order 13789, Identifying and Reducing Tax Regulatory Burdens, issued on April 21, 2017 (82 FR 19317) and the second report issued in response (82 FR 48013) (stating that the Treasury Department continues to analyze all recently issued significant regulations and is considering possible reforms of recent regulations, which include regulations under chapter 4).

Based on public input, and taking into account the burden-reducing policies described in Executive Orders 13777 and 13789, these regulations propose certain amendments to the regulations under chapters 3 and 4, including certain refund related issues for which comments were received. The Explanation of Provisions section of this preamble describes these proposed amendments and addresses public comments received in response to the Request for Information and Notice 2017–28, other than comments that would require a statutory change or