II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for NEUROPACE RNS SYSTEM is 3,796 days. Of this time, 2,694 days occurred during the testing phase of the regulatory review period, while 1102 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* June 26, 2003. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective was June 26, 2003.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* November 9, 2010. FDA has verified the applicant's claim that the premarket approval application (PMA) for NEUROPACE RNS SYSTEM (PMA P100026) was initially submitted November 9, 2010.

3. *The date the application was approved:* November 14, 2013. FDA has verified the applicant's claim that PMA P100026 was approved on November 14, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, the applicant seeks 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES** and **ADDRESSES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 9, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–12322 Filed 6–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0558]

Agency Information Collection Activities; Proposed Collection; Comment Request; Disclosures in Professional and Consumer Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled, ''Disclosures in Professional and Consumer Prescription Drug Promotion.''

DATES: Submit either electronic or written comments on the collection of information by August 14, 2017.

ADDRESSES: 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 August 14, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of August 14, 2017. 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.

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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–0558 for ''Disclosures in Professional and Consumer Prescription Drug Promotion.'' 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 Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, 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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jonnalynn Capezzuto, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the 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. ''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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Disclosures in Professional and Consumer Prescription Drug Promotion—OMB Control Number 0910—NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

FDA regulates prescription drug promotion directed to healthcare professionals (HCPs) and consumers (section 502(n) of the FD&C Act (21 U.S.C. 352(n)). In the course of promoting their products, pharmaceutical sponsors (sponsors) may present a variety of information including the indication, details about the administration of the product, efficacy information, and clinical trial data. In an effort to present often complicated information concisely, sponsors may not include relevant information in the body of the text or visual display of the claim. Additionally, sponsors may not always present limitations to the claim in the main body of the text or display. In these cases, sponsors typically include disclosures of information somewhere in the promotional piece.

There is little or no published research on disclosures in prescription drug promotion, either directed to consumers or to HCPs. Previous research on the effectiveness of disclosures has been conducted primarily in the dietary supplement arena (Refs. 1–4). Thus, the proposed research will examine the effectiveness of clear and conspicuous disclosures in prescription drug promotion directed to both of these populations. The purpose of our study is to determine how useful disclosures regarding prescription drug information are when presented prominently and adjacent to claims.[1] Specifically, are HCPs and consumers able to use disclosures to effectively frame information in efficacy claims in prescription drug promotion?

To address this research question, we have designed a set of studies that cover both consumers and HCPs, as well as three different types of claims: Scope of treatment, ease of use, and statistical significance (see table 1). The scope of treatment claim can be thought of as a disease-awareness claim; that is, a broader discussion of a medical condition that may include disease characteristics beyond what the promoted drug has been shown to treat, followed by a disclosure of this nature. The ease of use claim is a simple claim of easy drug administration that omits specific important details that contribute to a more difficult drug administration than suggested. Finally, the statistical significance claim will be

[1] The Federal Trade Commission (FTC), which regulates the advertising of non-prescription drug products as well as other non-FDA regulated products (*e.g.,* package goods, cars, etc.), issued a specific position on disclosures (Ref. 5) for the advertising it regulates. Specifically, FTC explains that disclosures must be ''clear and conspicuous''; in other words, in understandable language, located near the claim to be further clarified, and not hidden or minimized by small font or other distractions.

one in which the disclosure reveals that the presented analyses were not statistically significant, and thus must be viewed with considerable caution.

TABLE 1—IDENTICAL STUDY DESIGNS FOR SAMPLES OF HCPS AND CONSUMERS

Type of claim	Level of disclosure		
	Weak	Strong	Control
Study A: HCPs			
Scope of Treatment	Evidence Only	Evidence + Conclusion	None.
Ease of Use	Evidence Only	Evidence + Conclusion	None.
Statistical Significance	Evidence Only	Evidence + Conclusion	None.
Study B: Consumers			
Scope of Treatment	Evidence Only	Evidence + Conclusion	None.
Ease of Use	Evidence Only	Evidence + Conclusion	None.
Statistical Significance	Evidence Only	Evidence + Conclusion	None.

Each participant will view three different mock promotional print pieces for different prescription drug products. For each of the three promotional pieces, they will be randomized to see an ad with a weak disclosure, a strong disclosure, or no disclosure. We will manipulate the strength of disclosure by including additional concluding information (strong) or not (weak) in the disclosure statement. In all cases, disclosures will be adjacent to claims and written in font clear enough to be detected.

Technically speaking, these designs can be viewed as 3 within-subjects 1 × 3 designs with level of disclosure as a between subject factor. In other words, we will analyze the results of the scope of treatment disclosures independently of the ease of use disclosures and statistical significance disclosures, even though each participant will see one of each. The claims and disclosures are different enough that practice effects should be moderated, but we will counterbalance the order of ads shown to minimize potential bias.

Because promotional pieces intended for HCPs and consumers have different levels of complexity and medical depth, and because the amount of knowledge expected between the two groups differs, the studies will use separate mock promotional pieces and ask slightly different comprehension questions of each group. We will maintain as much similarity across groups as possible for descriptive comparisons.

Both consumers and HCPs will be recruited from Internet panels. Because promotional pieces will represent three different medical conditions, we will obtain a general population sample of consumers and a HCP sample of primary care physicians. Eligible participants who agree to participate will view mock promotional pieces and answer questions about their comprehension of the main messages in the promotion, perceptions of the product, attention to disclosures and intention to ask a HCP about it (consumers) or to prescribe the product (HCPs). Questionnaires are available upon request.

Pretests will be conducted before conducting the main studies in order to ensure the mock promotional pieces are realistic and that the questionnaire flows well and questions are reasonable. We will supplement the findings of the pretests with two small eye-tracking studies. Researchers use eye-tracking technology to capture viewing behavior that is independent of self-report. The technology measures where and for how long participants glanced at or examined particular parts of a display. It has been used in studies of consumer print advertising (Refs. 6–8) and Internet promotion (Refs. 9–10). To our knowledge, there is little or no published research using eye-tracking technology with HCPs.

We will use these small eye-tracking studies to determine what parts of each promotional piece consumers and HCPs actually viewed. Specifically, we will be able to determine whether they looked at the disclosure statement at all, and we can obtain a rough idea of how long they looked at it. This data will complement the self-reported items on the questionnaire. Moreover, we will use this data, as well as the pretest data, to improve the main studies. For this part of the study, 20 consumers and 20 HCPs will view the promotional pieces.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity [1]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
Consumers					
Pretest Screener	833	1	833	.03 (2 min.)	25
Pretest	500	1	500	0.33 (20 min.)	165
Eye-Tracking Screener	80	1	80	.08 (5 min.)	7
Eye-Tracking Study	20	1	20	1	20
Main Study Screener	2,500	1	2,500	.03 (2 min.)	75
Main Study	1,500	1	1,500	0.33 (20 min.)	495
HCPs					
Pretest Screener	735	1	735	.03 (2 min.)	22

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity [1]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
Pretest	500	1	500	0.33 (20 min.)	165
Eye-Tracking Screener	80	1	80	.08 (5 min.)	7
Eye-Tracking Study	20	1	20	1	20
Main Study Screener	2,206	1	2,206	.03 (2 min.)	67
Main Study	1,500	1	1,500	0.33 (20 min.)	495
Total					1,563

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Rounded to the next full hour.

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Dated: June 9, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–12329 Filed 6–13–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–2903]

Data and Methods for Evaluating the Impact of Opioid Formulations With Properties Designed To Deter Abuse in the Postmarket Setting: A Scientific Discussion of Present and Future Capabilities; Public Workshop; Issues Paper; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public workshop entitled ''Data and Methods for Evaluating the Impact of Opioid Formulations with Properties Designed to Deter Abuse in the Postmarket Setting: A Scientific Discussion of Present and Future Capabilities.'' The purpose of the public workshop is to host a scientific discussion with expert panel members and interested stakeholders about the challenges in using the currently available data and methods for assessing the impact of opioid formulations with properties designed to deter abuse on opioid misuse, abuse, addiction, overdose, and death in the postmarket setting. The goal of this meeting is to discuss ways to improve the analysis and interpretation of existing data, as well as to discuss opportunities and challenges for collecting and/or linking additional data to improve national surveillance and research capabilities in this area. To assist in the workshop discussion, FDA is making available an issues paper that provides a brief overview of the currently available data resources used for evaluating the impact of opioid formulations with properties designed to deter abuse; summarizes some of the key methodological issues in this area; and outlines the issues that we would like to discuss during the upcoming workshop, including enhancing existing resources, applying new methodology, and creating new resources.

DATES: The public workshop will be held on July 10 and 11, 2017, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by September 11, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 11, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 11, 2017. 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. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910. The hotel's phone number is 301–589–0800.

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