recommendations on supplemental biologics license application 125586/546 from AstraZeneca AB, submitted to confirm the clinical benefit of Andexxa (coagulation factor Xa (recombinant), inactivated -zhzo), for patients treated with rivaroxaban or apixaban when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before November 14, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 1:10 p.m. and 2:10 p.m. Eastern Time on November 21, 2024. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, along with the names, email addresses, and direct contact phone numbers of proposed participants, and an indication of the approximate time requested to make their presentation on or before 12 p.m. Eastern Time on November 6, 2024. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by 6 p.m. Eastern Time on November 8, 2024.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Cicely Reese at *CBERCTGTAC@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. No participant will be prejudiced by this waiver, and that the ends of justice will be served by allowing for this modification to FDA's advisory committee meeting procedures.

Dated: September 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–22561 Filed 10–1–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3653]

Agency Information Collection Activities; Proposed Collection; Comment Request; Promotion of Prescription Drugs Within a Talk Show Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with a proposed study entitled ''Promotion of Prescription Drugs Within a Talk Show Format.''

DATES: Either electronic or written comments on the collection of information must be submitted by December 2, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 2, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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):* 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–2024–N–3653 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Promotion of Prescription Drugs Within a Talk Show Format.'' 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, 240–402–7500.

• 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.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAstaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), 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.

Promotion of Prescription Drugs Within a Talk Show Format

(OMB Control Number 0910—NEW)

This information collection request supports Agency research authorized by section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) and section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)).

The mission of the Office of Prescription Drug Promotion (OPDP) is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated so that patients and healthcare providers can make informed decisions about treatment options. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission, focusing in particular on three main topic areas: advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features, we assess how elements such as graphics, format, and the characteristics of the disease and product impact the communication and understanding of prescription drug risks and benefits. Focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience. Our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first topic area, advertising features, by examining a form of advertising known as native advertising.

Because we recognize that the strength of data and the confidence in the robust nature of the findings are improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our home page at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research,* which includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office.

The objective of this present research is to conduct experimental studies to examine issues related to endorsers in direct-to-consumer prescription drug promotion that occurs within a talk show format. This study complements and builds upon two prior FDA studies on endorsement issues (OMB control numbers 0910–0894 and 0910–0918). The first study examined a number of different endorser types in print or internet settings and focused on examining how various disclosures of the payment status of the endorser influenced audience reactions. The second study extended the prior research by examining, among other

things, audience reactions to actual-use disclosures (*e.g.,* ''actor portrayal'' versus ''actual patient'') in a different medium, television ads. The currently proposed study will focus on endorsers in a native advertising format (*i.e.,* talk show).

Native advertising is a form of advertisement where marketers present paid content in a format designed to look and feel like the surrounding media format and content in which it appears (Refs. 1 and 2). Native advertisements have become an increasingly popular form of advertising. In 2023, advertisers in the United States were expected to spend $97.46 billion on native display advertising in all product categories (showing a product in a combination of image, text, and graphics), accounting for 59.7 percent of total display advertising spending (Ref. 2). The intent of native advertising is to minimize the disruption in the consumer's regular media intake experience (Ref. 3). Recently, FDA has issued compliance letters to pharmaceutical firms for misleading promotion of prescription drug products within talk show formats (Refs. 11 and 12).

Research on the native advertising format extends the theoretical understanding of persuasion knowledge (Refs. 4 to 6) and advertisement recognition (Ref. 7) and has evaluated policy implications around deceptive advertising across different media platforms (Refs. 8 and 9). However, there has been less study of perceptions and attitudes resulting from native advertising, such as the impact on viewer perceptions toward the product, the advertisement, the endorser, or the interaction of these factors (Ref. 10). Moreover, the majority of research on native advertising appears to focus on advertorials in print or product placement (Refs. 1 to 7). In the literature, we did not find peer-reviewed studies examining attitudes and perceptions in reaction to native advertising in a talk show format.

In the research described here, we will investigate a native advertisement for a fictitious prescription drug for type 2 diabetes embedded in a health-themed television talk show. This examination will help close the gap in the literature. We will examine the impacts of three independent variables—(1) sponsorship prominence (none, once, periodic, constant); (2) endorser type (the guest on the talk show: patient, physician); and (3) risk prominence (lower, higher)—on the recall and comprehension of risks and benefits depicted in the advertisement, perceptions of endorser characteristics, perceptions of drug qualities, and behavioral intentions. The four sponsorship prominence conditions will be: (1) no disclosure; (2) disclosure once at the beginning of the segment ([GUEST NAME] is a paid spokesperson for DRUG X); (3) periodic disclosure at the beginning, middle, and end of the segment (A reminder that [GUEST NAME] is a paid spokesperson for DRUG X); and (4) constant disclosure in text at the bottom of the screen through the entire segment ([GUEST NAME] is a paid spokesperson for DRUG X). The two endorser type conditions will vary by type of talk show guest: a patient or a physician. Studying sponsorship prominence and endorser type allows us to extend our prior research on endorsers in print and online promotion (OMB control numbers 0910–0894 and 0910–0918) to native advertisements in a talk show format. Another factor that could affect whether viewers perceive a native advertisement for a prescription drug in a talk show format as advertising is the prominence of the risk disclosure. The two risk prominence conditions will vary by lower or higher prominence: (1) discussed in question-and-answer format during the interview or (2) text scroll with voiceover after the interview has concluded.

To ensure that the study is operating as planned, we will conduct a pretest prior to launching the main study. Both the pretest and main study will use a $2 \times 4 \times 2$ factorial design (table 1). Through the use of an online survey, each respondent will view 1 of 16 experimental variations of a fictitious health-themed television show. This base program will be consistent across experimental conditions and will feature content that blends health, wellness, and lifestyle topics. The target native advertisement segment will be embedded between the base program segments, varying across the three independent variables.

Respondents will be recruited from web panels and include those who have been diagnosed with type 2 diabetes, live in the United States, and are fluent in English. Participation in the study is voluntary. We will not select respondents who work for the U.S. Department of Health and Human Services or a pharmaceutical, advertising, or market research company.

TABLE 1—STUDY EXPERIMENTAL DESIGN

Sponsorship prominence	Endorser type and risk prominence			
	Patient guest		Physician guest	
	Higher risk prominence	Lower risk prominence	Higher risk prominence	Lower risk prominence
None.				
Once.				
Periodic.				
Constant.				

Following the video, respondents will be asked questions pertaining to their recall and comprehension of risks and benefits depicted in the advertisement, perceptions of endorser characteristics, perceptions of drug qualities, and behavioral intentions.

We estimate the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
Pretest					
Pretest Screener Completes	400	1	400	0.03 (2 minutes)	12
Pretest Questionnaire Completes	80	1	80	0.30 (18 minutes)	24
Main Study					
Main Study Screener Completes	3,200	1	3,200	0.03 (2 minutes)	96
Main Study Questionnaire Completes	640	1	640	0.30 (18 minutes)	192
Total					324

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

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. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Wojdynski, B.W. and G.J. Golan, ''Native Advertising and the Future of Mass Communication,'' *American Behavioral Scientist,* vol. 60, pp. 1403–1407, 2016, *https://doi.org/10.1177/0002764216660134*.
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3. Campbell, C. and L.J. Marks, ''Good Native Advertising Isn't a Secret,'' *Business Horizons,* vol. 58, pp. 599–606, 2015, *https://doi.org/10.1016/j.bushor.2015.06.003*.
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8. Hastak, M. and M.B. Mazis, ''Deception by Implication: A Typology of Truthful but Misleading Advertising and Labeling Claims,'' *Journal of Public Policy & Marketing,* vol. 30, pp. 157–167, 2011, *http://www.jstor.org/stable/23209271*.
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10. Lee, S.S., H. Chen, and Y.-H. Lee, ''How Endorser-Product Congruity and Self-Expressiveness Affect Instagram Micro-Celebrities' Native Advertising Effectiveness,'' *Journal of Product & Brand Management,* vol. 31, pp. 149–162, 2022, *https://www.emerald.com/insight/content/doi/10.1108/JPBM-02-2020-2757/full/html*.

*11. Untitled Letter to Aclaris Therapeutics, Inc. (June 14, 2019). Available at: *https://www.fda.gov/media/128151/download?attachment*.

*12. Untitled Letter to Biohaven Pharmaceuticals (March 8, 2021). Available at: *https://www.fda.gov/media/146528/download?attachment*.

Dated: September 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–22575 Filed 10–1–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–1105]

Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers.'' The guidance provides information for sponsors, clinical investigators, institutional review boards (IRBs), contract research organizations (CROs), and other interested parties on the use of electronic systems, electronic records, and electronic signatures in clinical investigations of foods, medical products, tobacco products, and new animal drugs. The guidance provides recommendations regarding the requirements in our regulations, pursuant to which FDA considers electronic systems, electronic records, and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper. This guidance finalizes the draft guidance of the same title issued on March 16, 2023, and supersedes the guidance for industry entitled ''Computerized Systems Used in Clinical Investigations'' issued in May 2007.