[2] These figures were calculated by the U.S. Department of Health and Human Services, Administration for Children and Families, Office of Community Services, Division of Energy Assistance by multiplying the estimated state median income for a four-person family for each state by 60 percent.

[3] To adjust for different sizes of households for LIHEAP purposes, 45 CFR 96.85 calls for multiplying 60 percent of a state's estimated median income for a four-person family by the following percentages: 52 percent for a one-person household, 68 percent for a two-person household, 84 percent for a three-person household, 100 percent for a four-person household, 116 percent for a five-person household, and 132 percent for a six-person household. For each additional household member above six people, 45 CFR 96.85 calls for adding 3 percentage points to the percentage for a six-person household (132 percent) and multiplying the new percentage by 60 percent of the median income for a four-person family.

Note: FFY 2015 covers the period of October 1, 2014, through September 30, 2015. The estimated median income for four-person families living in the United States for this period is $76,365. Grantees that use SMI for LIHEAP may, at their option, employ such estimates at any time between the date of this publication and the later of October 1, 2014 or the beginning of their fiscal year.

Statutory Authority: 45 CFR 96.85(b) and 42 U.S.C. 8624(b)(2)(B)(ii).

Dated: July 15, 2014.

Jeannie L. Chaffin,

Director, Office of Community Services.

[FR Doc. 2014–17063 Filed 7–18–14; 8:45 a.m.]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1151]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Direct-to-Consumer Promotion Directed at Adolescents

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 20, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title, ''Experimental Study of Direct-to-Consumer (DTC) Promotion Directed at Adolescents.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Experimental Study of Direct-to-Consumer (DTC) Promotion Directed at Adolescents—(OMB Control Number 0910—NEW)

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes 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(d)(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.

Sponsors for several prescription drug classes market their products directly to vulnerable groups, including adolescents. Such DTC marketing to adolescents raises a variety of potential concerns. Adolescents are a unique audience for DTC drug marketing because their cognitive abilities are different than those of adults, and they are usually dependent on adults for health insurance coverage, health care provider access, and prescription drug payment. Despite this uniqueness, research regarding how adolescents use risk and benefit information for health-related decisions is limited. If considered at all in healthcare communication research, age is typically treated as simply another segment of the audience (Ref. 1), and researchers fail to consider how *information processing* (how people understand information) in response to advertisement (ad) exposure might differ among adolescents versus older viewers.

The FD&C Act requires manufacturers, packers, and distributors that advertise prescription drugs to disclose certain information about a product's uses and risks to potential consumers in all advertisements. Consumers must consider tradeoffs with regard to the product's risks and benefits in deciding whether to ask their health care professionals about the product. Presenting technically factual information is important, but other factors can also affect potential consumers. Information processing capacity, the relevance and vividness of the information, and contextual factors such as family dynamics likely affect how adolescent consumers weigh the potential risks and benefits of using a product.

Despite the lack of previous research specific to DTC drug marketing to adolescents, existing theoretical and empirical data make a strong case for treating adolescence as a unique life stage during which vulnerabilities that can affect informed decisionmaking must be taken into account. Well-known theories of adolescent development have long pointed to developmental changes that occur during the transitional period as an individual moves from childhood to young adulthood (Ref. 2). For instance, Erikson (Refs. 3, 4) describes an often turbulent psychosocial crisis that occurs as adolescents strive to develop their unique identity. Piaget (Refs. 5, 6) and Kohlberg (Ref. 7) describe changes in stages relative to cognitive processing and reasoning that occur in this period, as the adolescent becomes increasingly capable of more abstract thinking. Different cognitive, social and emotional, and developmental processes in the adolescent brain mature simultaneously and at different rates, affecting decisionmaking by age. All of these factors can influence how adolescents perceive and process information as well as weigh risks and benefits.

The need for understanding how adolescents weigh risks and benefits is particularly critical given the potential adverse events associated with use of the drug classes that are marketed directly to adolescents. Suicide and suicidal ideation has been associated with some of these classes, including a commonly used class of acne medications. The risk and benefit information needs to be clearly presented in ways that adolescents can understand. Interpretation of more

subtle messages in the advertisements, along with the lens through which adolescents view the message, must be understood. For example, given the potential stigma of acne and adolescents' heightened concerns about peer perceptions, marketing that emphasizes these two features in subtle ways might minimize the attention given to any risk information provided. This suggests the need to systematically explore the role of various factors that would be expected to influence adolescent decision-making, such as peer and family perceptions of stigma.

We plan to conduct a randomized, controlled study in two different medical conditions that assesses adolescents' perceptions following exposure to different types of DTC prescription drug advertising. We plan to compare adolescents' perceptions to those of young adult counterparts. Each participant will view a Web-based promotional campaign for either a fictitious Attention Deficit Hyperactivity Disorder (ADHD) medication or a fictitious acne medication. Because adolescents typically depend on their parents for prescription drug purchases, we also will include a sample of parents matched to their adolescent children to explore similarities and differences in perceptions for these matched pairs.

Within the two medical conditions, we propose to explore the role of three different factors that may influence adolescent understanding and perceptions of DTC. Two of these factors include timing issues: The timing of the onset of benefits and the timing of the onset of risks. Adolescents may be particularly likely to give more credence to benefits that occur immediately and may be likely to discount risks that do not occur immediately. Research suggests that the frontal lobe, which controls self-regulatory functions, is not fully developed until the mid-20s (Ref. 8), which may lead to difficulty in impulse control and planning, and thus decisionmaking. Other research suggests that adolescents are more likely to engage in risky behavior, although whether they do this because they discount their own likelihood of experiencing risks or if they cannot help themselves despite having adequate perceptions of their own vulnerability has not been determined (Refs. 9, 10). Given the variety of prescription drug products on the market with varying benefit and risk profiles, these factors (benefit and risk timing) will enable us to investigate its role in adolescent processing of DTC ads.

We also propose to determine whether the severity of the risk within each condition influences adolescent decisionmaking in relation to DTC ads. Risk perceptions and risk taking have been active topics of exploration with regard to adolescents and thus the severity of the risks may play a role in determining whether and how adolescents attend to the benefit-risk profile of the prescription drugs they see advertised. This factor will also help us generalize further to different types of products, although we recognize that it will not cover the gamut of prescription drug products.

Although the variables we are examining are all attributes of the drug products themselves and do not reflect particular behaviors of sponsors, this information will be crucial in determining what types of prescription drugs may require additional care when advertising them to adolescents. One strength of the proposed study is that with two different medical conditions and multiple different variations in the benefit and risk profiles of the drugs, we will obtain a good representation of adolescent response to DTC ads. Moreover, in comparing adolescents with adults, we will have a better idea of how perceptions and understanding of benefits and risks in DTC ads differ across this part of the lifespan.

Within each of the two medical conditions, we will randomly assign participants to one of a number of experimental conditions. We propose for each medical condition a 2 (risk onset: immediate, delayed) × 2 (benefit onset: immediate, delayed) × 2 (risk severity: high, low) factorial design, based on the rationale in the prior section.

We will use the same risk (within medical conditions) to control for differences in severity (e.g. dry skin vs. cancer) and avoid confounds.

TABLE 1—EXPERIMENTAL CONDITIONS WITH THREE INDEPENDENT VARIABLES

Comparison group	Variable 1: Timing of risk: Immediate				Variable 1: Timing of risk: Delayed			
	Variable 2: Severity of risk (low)		Variable 2: Severity of risk (high)		Variable 2: Severity of risk (low)		Variable 2: Severity of risk (high)	
	Variable 3: Timing of benefit (immediate)	Variable 3: Timing of benefit (delayed)	Variable 3: Timing of benefit (immediate)	Variable 3: Timing of benefit (delayed)	Variable 3: Timing of benefit (immediate)	Variable 3: Timing of benefit (delayed)	Variable 3: Timing of benefit (immediate)	Variable 3: Timing of benefit (delayed)
Study 1 (Medical Condition A, Acne)								
Younger adolescents (13–15)	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	Group 7	Group 8.
Older adolescents (16–19)	Group 9	Group 10	Group 11	Group 12	Group 13	Group 14	Group 15	Group 16.
Young adults (25–30)	Group 17	Group 18	Group 19	Group 20	Group 21	Group 22	Group 23	Group 24.
Parents	Group 25	Group 26	Group 27	Group 28	Group 29	Group 30	Group 31	Group 32.
Study 2 (Medical Condition B, ADHD)								
Younger adolescents (13–15)	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	Group 7	Group 8.
Older adolescents (16–19)	Group 9	Group 10	Group 11	Group 12	Group 13	Group 14	Group 15	Group 16.
Young adults (25–30)	Group 17	Group 18	Group 19	Group 20	Group 21	Group 22	Group 23	Group 24.
Parents	Group 25	Group 26	Group 27	Group 28	Group 29	Group 30	Group 31	Group 32.

We will conduct the studies with two medical conditions that have particular relevance for adolescents—acne and ADHD. For ADHD, we will target a sample that has been diagnosed with the condition. If an appropriate sample size cannot be obtained, we will extend the sample by including adolescents with family members who have been diagnosed with ADHD to help ensure participants are interested in and paying attention to the topic. Since acne is

relevant for large numbers of people, it seems reasonable to draw the study sample from the general population. Both conditions have particular relevance for adolescents.

The study will enroll three specific age groups (13 to 15, 16 to 19, and 25 to 30 year-olds). We propose to explore differences in effects of the ad manipulations across these three age groups on a variety of outcomes, including benefit and risk recall, benefit and risk perceptions, and behavioral intentions. Certain ads may communicate more or less effectively with specific age groups. The presentation of immediate versus delayed risks, for example, might differentially affect teens and young adults. Additionally, we propose to examine factors unique to adolescent healthcare including relationship between parent and child, issues of stigma, and risk taking.

We will also recruit parents of the two younger age groups into the sample to explore potential differences between teen and parental perceptions. There are three reasons for including parents in the sample:

1. Adolescents and adults bring varied experiences and developmental capacities to everyday decisions. As a result, they may differ both in their perceptions of risks and benefits and in their evaluations of DTC. Matching parents and adolescents in the sample will allow us to conduct additional analyses to explore similarities and differences between parental and adolescent perceptions. By including parents of both younger and older adolescents, we can compare these groups to see if there are differences in parent-child risk-perception concordance/discordance across adolescence as a function of age.

2. Parents will serve as a fourth age group, which will allow us to conduct additional comparisons between the age categories. Increasing the number of age categories will allow us to look for differences between a greater range of age groups, and to see if clear patterns of age differences exist (e.g., it could be that the most significant differences are observed when comparing young adolescents and those over 30 years of age).

3. Including parent-child dyads will address the need for empirical data comparing adolescents' and their parents' evaluations of DTC prescription drug advertising.

Select experimental conditions will be pretested with 920 participants to assess questionnaire wording and implementation. Based on power analyses, the main study will include 5,120 completed participants, which will allow us enough power to test several possible covariates (factors other than our manipulated variables) that may have effects, such as demographic information.

The protocol will take place via the Internet. Participants will be randomly assigned to view one Web site ad for a fictitious prescription drug that treats either acne or ADHD and will answer questions about it. The entire process is expected to take no longer than 35 minutes. This will be a one-time (rather than annual) collection of information. The questionnaire is available upon request.

In the **Federal Register** of October 31, 2013 (78 FR 65326), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comment submissions. We outline the observations and suggestions raised in the two submissions and provide our responses:

(Comment 1) One comment mentioned that the document states the FDA will examine ''adolescents' perceptions following exposure to different types of DTC prescription drug advertising'' and asked if the Agency can clarify what ''types'' of ads will be studied? In particular, will Internet display ads, social media ads (e.g., Facebook), and mobile ads be considered?

(Response) As stated in the 60-day notice, participants will be randomly assigned to view one Web site ad for a fictitious prescription drug that treats either acne or ADHD. This ad will be similar to current Web site advertisements produced for pharmaceutical companies; however, all content will be on a single page, without active links to subpages. On the Web page, there will be an embedded video that resembles a television ad.

(Comment 2) One comment mentioned that the document states ''The protocol will take place via the Internet. Participants will be randomly assigned to view one Web site ad for a fictitious prescription drug that treats either acne or ADHD and will answer questions about it.'' The commenter mentions that it appears that FDA will be specifically looking at Internet display ads and that FDA seems mainly concerned with ''timing issues'' that are not applicable to ''Web based'' promotional campaigns unless these are video campaigns, which can be YouTube campaigns or merely TV ads embedded in Web pages. The commenter asks for clarification.

(Response) To present the stimuli, we will produce a series of fictitious advertisements using a Web format with embedded video that are comparable to current advertisements produced for pharmaceutical companies. The ''timing issues'' that are being manipulated in the study are not related to timing of the presentation of the information in the ads, but to the adolescents' perception of the timing of the onset of benefits and the timing of the onset of risks of the drugs. We are specifically interested in learning whether adolescents are more likely than adults to give more credence to benefits that occur immediately and to discount risks that do not occur immediately.

(Comment 3) One comment mentions modifying the sample by including groups of symptomatic/undiagnosed adolescents and their parents in the study design because perception of risk may vary depending on whether an individual is diagnosed or not. The commenter states that diagnosed adolescents who are taking medication and who experience no side effects may be less sensitized to risk (just as their adult counterparts tend to be), because once they have experienced a medication with no accompanying side effects, the possibility of risk may seem more remote.

(Response) We agree that perception of risk may vary depending on whether or not an individual is diagnosed with the condition. In our design, adolescents do not have to have a medical diagnosis of acne to participate in the study. Because acne is a visible and commonly self-diagnosed condition, it is reasonable to include non-diagnosed individuals with acne in the study. However, for the ADHD condition, we aim to enroll only adolescents who are diagnosed with ADHD to avoid the potential confusions for ''lay'' or self-diagnosis of the condition.

(Comment 4) One comment mentions modifying the sample by including groups of symptomatic/undiagnosed adolescents and their parents in the study design because it will help better understand what the primary impact of DTC is on teens and to what extent DTC functions to help teens self-identify with a condition vs. advocate for a brand.

(Response) Although we agree that it would be interesting to examine the extent to which DTC advertising functions to help teens self-identify with a condition vs. advocate for a brand, this question is beyond the scope of this study. The ads used in this study are intended to assess risk perceptions in DTC ads, not to examine identity measures, brand recognition or advocacy.

(Comment 5) One comment mentions modifying the sample by including subsets of diagnosed teens who are currently medicating for ADHD, vs. nonmedicating, and, as part of the exit interview, capture data on those who have experienced side effects from medication, vs. those who have not.

(Response) We agree that we should include teens who are both currently medicating and nonmedicating. Although we are not screening participants based upon their medication status, we will be asking participants about their current and past use of medications and will explore this as part of our analysis. We also agree that it would be interesting to explore differences for teens who have experienced side effects and those who have not experienced side effects since experience with side effects might affect perception of the risk of the drugs in the study. Based upon this recommendation, we will add an item to the instrument to measure the participants' previous experience with side effects from medications. This item will serve as a moderator variable.

(Comment 6) One comment mentions not supplementing the sample with siblings of teens diagnosed with ADHD because they believe that adolescents who do not suffer from the symptoms of ADHD cannot truly evaluate the benefits of a treatment vs. its risk, in the absence of experiencing the symptoms first hand.

(Response) We agree that it is desirable to recruit a sample of adolescents who have been diagnosed with ADHD; therefore, we do not currently plan to recruit adolescents who have not been diagnosed with the condition. Preliminary estimates lead us to believe that we will be able to recruit a sufficient sample of adolescents who are diagnosed with ADHD. If, however, an appropriate sample size cannot be obtained, we plan to extend the sample by including adolescents with family members who have been diagnosed with ADHD rather than adolescents who are not at all familiar with the condition.

(Comment 7) One comment mentions modifications to topic areas to include questions about the role of teens in the decision to seek diagnosis, to medicate (or not), and the actual brand decision because it is also important to understand this processing within the context of the entire patient pathway.

(Response) We agree that it is important to know more about the role of teens in the decision to seek diagnosis, whether or not to medicate, and the actual brand decision. It is beyond the scope of this study to look at decisions regarding teens' roles in seeking diagnosis and brand decisionmaking. Our study does explore teen roles in decisionmaking about use of medication through the following questions:

1. Who would make the final decision about whether you would use this drug? (you/your [PARENT RELATIONSHIP]/you and your [PARENT RELATIONSHIP] together);
2. My [PARENT RELATIONSHIP] lets me decide what prescription medication I should or shouldn't take (scale ranging from always to never); and
3. My [PARENT RELATIONSHIP] asks me my preference when we discuss taking different medications (scale ranging from always to never).

(Comment 8) One comment mentions modifications to topic areas to include questions about the relative importance of various sources of information that impact teen perceptions of treatment options because teens consume media differently than their adult counterparts.

(Response) Although we agree that the relative importance of and preferences for various sources of information may affect the perception of treatment options, exploration of this topic is outside the scope of our current study.

(Comment 9) One comment mentions considering supplemental research methodologies because direct questioning does not always provide an accurate reflection of real-world behavior and to further bolster the findings of this study, consider engaging teen experts to study teens on behalf of FDA.

(Response) We agree with the comment that direct questioning does not always provide an accurate reflection of real-world behavior. To that end, we engaged 19 to 20 year-old college students as part of a teen ''expert'' work group during the development of the measurement instrument for this study in order to obtain items that provide the most accurate reflection possible. The teen/young adult consultants provided feedback on the measures and suggestions for revisions. Further involvement of teen ''experts'' would require a formal qualitative component of the study that we are unable to conduct at this time. However, a qualitative study to further explore decision making among teens could be a useful area for future research.

(Comment 10) One comment mentions considering supplemental research methodologies because in order to gain an accurate read on the processing of risk/benefit information, the stimuli should be depicted as realistically as possible and accurately reflect typical DTC in the category targeted to 13 to 17 year-olds.

(Response) We agree that it is important to depict the stimuli as realistically as possible. We will be modeling the stimuli after DTC ads being presented currently on the Web and on television, using similar language, graphic design techniques, and voiceover scripts. In addition, we will be attentive to current marketing norms with regard to selection of locations, wardrobe, and actors for the video ads.

FDA estimates 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	Total hours
Cognitive interviews	30	1	30	1.5 (90 min.)	45
Pretest 1 screener	8,730	1	8,730	.08 (5 min.)	698
Pretest 2 screener	1,930	1	1,930	.08 (5 min.)	154
Main study screener (acne)	7,142	1	7,142	.08 (5 min.)	571
Main study screener (ADHD)	43,086	1	43,086	.08 (5 min.)	3,447
Pretest 1 (420/medical condition)	900	1	900	0.5 (30 min.)	450
Pretest 2 (20/medical condition)	200	1	200	0.5 (30 min.)	100
Main study, 13–15 year-olds (both acne and ADHD)	1,300	1	1300	0.5 (30 min.)	650
Main study, 16–19 year-olds (both acne and ADHD)	1,300	1	1300	0.5 (30 min.)	650
Main study, young adults (both acne and ADHD)	1,300	1	1300	0.5 (30 min.)	650
Main study, parents (both acne and ADHD)	1,300	1	1300	0.5 (30 min.)	650

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

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Number of pretest/study completes	6,300				
Total					8,065

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

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Dated: July 15, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–16998 Filed 7–18–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0998]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection in the regulations for in vivo radiopharmaceuticals used for diagnosis and monitoring.

DATES: Submit either electronic or written comments on the collection of information by September 19, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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, including each proposed extension of an existing 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.

Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring—21 CFR Part 315—(OMB Control Number 0910–0409)—Extension

FDA is requesting OMB approval of the information collection requirements contained in 21 CFR 315.4, 315.5, and 315.6. These regulations require manufacturers of diagnostic radiopharmaceuticals to submit information that demonstrates the safety and effectiveness of a new diagnostic radiopharmaceutical or of a new