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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1151]

Agency Information Collection Activities; Proposed Collection; 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 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, ''Experimental Study of Direct-to-Consumer (DTC) Promotion Directed at Adolescents.'' This study is designed to examine how adolescents interpret DTC advertising directed at them.

DATES: Submit written or electronic comments on the collection of information by December 30, 2013.

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 Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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.

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

Regulatory Background

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.

Adolescents and DTC

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 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 decision-making 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 identify. 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 decision-making 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.

Research Purpose

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 decision-making. 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 decision-making in relation to DTC. 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.

Design Overview

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.

TABLE 1—EXPERIMENTAL CONDITIONS WITH THREE INDEPENDENT VARIABLES—Continued

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)
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 acne, we will target a sample that has been diagnosed with, or, through self-report, has experienced the condition. For ADHD, we will target a sample that has been diagnosed with the condition. If an appropriate sample size cannot be obtained for ADHD, 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.

The study will enroll three specific age groups (13–15, 16–19, and 25–30). 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 having parents of two age groups, 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 1061 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 30 minutes. This will be a one-time (rather than annual) collection of information.

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
Pretest 1 screener (½ acne, ½ ADHD)	2,812	1	2,812	.08 (5 min.)	225
Pretest 2 screener (all one illness)	6,400	1	6,400	.08 (5 min.)	512
Main study screener (acne)	6,400	1	6,400	.08 (5 min.)	512
Main study screener (ADHD)	25,600	1	25,600	.08 (5 min.)	2,048
Pretest 1	450	1	450	0.5 (30 min.)	225
Pretest 2	700	1	700	0.5 (30 min.)	350
Main study, 13–15 year olds (both acne and ADHD).	1,300	1	1,300	0.5 (30 min.)	650
Main study, 16–19-year olds (both acne and ADHD).	1,300	1	1,300	0.5 (30 min.)	650
Main study, young adults (both acne and ADHD)	1,300	1	1,300	.5 (30 min.)	650
Main study, parents (both acne and ADHD)	1,300	1	1,300	.5 (30 min.)	650
Total pretest/study participants	6,350				

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
Total					6,472

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

The total respondent sample for this data collection is 6,350, including the two pretests. We estimate the response burden to be 30 minutes, for a total collection burden, including screeners, of 6,472 hours.

References

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Dated: October 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0618]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Products

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 December 2, 2013.

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 0910–0025. 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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.

Electronic Products—21 CFR Parts 1002 Through 1010 (OMB Control Number 0910–0025)—Extension

Under sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360ii through 360ss), FDA has the responsibility to protect the public from unnecessary exposure of radiation from electronic products. The regulations issued under these authorities are listed in Title 21 of the Code of Federal Regulations, chapter I, subchapter J, parts 1000 through 1050 (21 CFR parts 1000 through 1050).

Section 532 of the FD&C Act directs the Secretary of the Department of Health and Human Services (the Secretary), to establish and carry out an electronic product radiation control program, including the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products. The program is designed to protect the public health and safety from electronic radiation, and the FD&C Act authorizes the Secretary to procure (by negotiation or otherwise) electronic products for research and testing purposes and to sell or otherwise dispose of such products. Section 534(g) of the FD&C Act directs the Secretary to review and evaluate industry testing programs on a continuing basis; and section 535(e) and (f) of the FD&C Act directs the Secretary to immediately notify manufacturers of, and ensure correction of, radiation defects or noncompliance with performance standards. Section 537(b) of the FD&C Act contains the authority to require manufacturers of electronic products to establish and maintain records (including testing records), make reports, and provide information to determine whether the manufacturer has acted in compliance.

The regulations under parts 1002 through 1010 specify reports to be provided by manufacturers and distributors to FDA and records to be maintained in the event of an investigation of a safety concern or a product recall. FDA conducts laboratory compliance testing of products covered by regulations for product standards in parts 1020, 1030, 1040, and 1050.

FDA details product-specific performance standards that specify information to be supplied with the product or require specific reports. The information collections are either specifically called for in the FD&C Act or were developed to aid the Agency in performing its obligations under the FD&C Act. The data reported to FDA and the records maintained are used by