Marvel line of children's multivitamin and mineral dietary supplements: (1) Disney Princess Complete; (2) Disney Princess Gummies; (3) Disney Pixar Cars Gummies; (4) Disney Winnie the Pooh Gummies; (5) Disney Tigger & Pooh Gummies; (6) Disney Pixar Finding Nemo Gummies; (7) Disney Pixar Wall-E Gummies; (8) Disney Pixar Toy Story Gummies; (9) Marvel Heroes Complete; and (10) Marvel Heroes Gummies (collectively, the "NBTY Products").

According to the FTC complaint, Respondents represented, in advertisements, that the NBTY Products contained a significant amount of DHA (docosahexaenoic acid, a polyunsaturated Omega-3 fatty acid) or an amount comparable to 100 mg of DHA. The complaint alleges that this claim is false or misleading because, in fact, a daily serving of the NBTY products only contained either 0.1 mg of DHA (which is one thousandth of 100 mg) or 0.05 mg of DHA (which is five ten-thousandths of 100 mg).

The Commission also charges that Respondents represented that the DHA provided by a daily serving of the NBTY Products promoted healthy brain and eye development in children two years of age and older. The FTC alleges that this claim is false or misleading because Respondents failed to have evidence to substantiate it.

The proposed consent order contains provisions designed to prevent Respondents from engaging in similar acts and practices in the future. Part I of the proposed order prohibits Respondents from misrepresenting that any product contains a specific ingredient or specific numerical amount of any ingredient.

Part II of the proposed order prohibits Respondents from making any representations in advertising for any product about the health benefits, performance, or efficacy of the product, unless the representation is true and non-misleading. In addition, Respondents must possess competent and reliable scientific evidence sufficient in quality and quantity, when considered in light of the entire body of relevant and reliable scientific evidence, to support such claims as true.

Part III of the proposed order states that the order does not prohibit Respondents from making representations for any drug that are permitted in labeling for that drug under any tentative or final standard promulgated by the FDA, or under any new drug application approved by the FDA. This part of the proposed order also states that the order does not prohibit Respondents from making representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Part IV of the proposed order requires Respondents to pay two million, one hundred thousand dollars ($2,100,000) to the Commission to be used for equitable relief, including restitution, consumer redress, and any attendant expenses for the administration of such equitable relief.

Parts V through VIII of the proposed order require Respondents to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain personnel; to notify the Commission of changes in corporate structure that might affect compliance obligations under the order; and to file compliance reports with the Commission. Part IX provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify their terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2010–31823 Filed 12–17–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0420]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Testing Communications on FDA-Regulated Products Used in Animals

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 January 19, 2011.

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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–New and title "Testing Communications on FDA–Regulated Products Used in Animals." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Johnny Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *Juanmanuel.vilela@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.

Testing Communications on FDA–Regulated Products Used In Animals—(OMB Control Number 0910–New)

FDA's Center for Veterinary Medicine (CVM) has authorization under section 903(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) to conduct educational and public information programs relating to the safety of CVM-regulated products. Further, CVM is authorized to conduct this needed research to ensure that these programs have the highest likelihood of being effective. Thus, CVM concludes that improving communications about the safety of regulated animal drugs, feed, food additives, and devices will involve many research methods, including individual in-depth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys.

The information collected will serve three major purposes. First, as formative research, it will provide critical knowledge needed about target audiences to develop messages and campaigns about the use of animal drugs, feed, food additives, and devices. Knowledge of both the consumer and the veterinary professional decision-making processes will provide a better understanding of target audiences that FDA will need in order to design effective communication strategies, messages, and labels. These communications will aim to improve public understanding of the risks and benefits of using regulated animal drugs, feed, food additives, and devices by providing users with a better context in which to place risk information more

completely. Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents will be asked to give their reaction to the messages in either individual or group settings. Third, as evaluative research, it will allow FDA to ascertain the effectiveness of the messages and the distribution method of these messages in achieving the objectives of the message campaign. Evaluation of campaigns is a vital link in continuous improvement of communications at FDA.

In the **Federal Register** of August 19, 2010 (75 FR 51271), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received comments from two individuals and one trade association. FDA acknowledges one request for additional details on the necessity and purpose of the information to be collected, but notes that comments were invited on FDA's request for a generic clearance related to the formative testing of communications about veterinary products and products for animals. Under this generic clearance, details of individual studies (research questions, target audiences, methodologies, and consultants) will be tailored to specific communications-related questions. For each study FDA requests under this clearance, FDA will provide OMB with these details on the information collection. The communication development process will inform the purpose of the data collection and the means by which the data will be collected. For very early message development, qualitative research such as in-depth interviews or focus groups will be appropriate. At later communication development stages, more quantitative data collection would be more useful. FDA plans to use the data collected under this generic clearance to inform its communications campaigns. The data will not be used for the purposes of making policy or regulatory decisions.

Audience targets are also informed by the specific research question. Nonetheless, FDA provided more information by specifying some of the groups more likely to be targeted in tasks under this generic clearance, including: Consumers, pet owners, large animal producers, veterinarians, animal distributors, pet shop owners, stockyards staff and owners, abattoir owners or staff, grocery meat purchasers, agricultural extension agents, and professors of food science and related fields.

Furthermore, comments related to ways to enhance the data collection and to assess FDA's estimate of burden indicated that FDA should not limit itself to in-house expertise. FDA acknowledges that assistance may be requested from experts in other Government agencies. Depending on the specific research question to be addressed, FDA may consult experts in the United States Department of Agriculture and the United States Environmental Protection Agency.

FDA received a comment relating to the cruelty and sadism of animal testing. In response to this comment, FDA notes that its notice was for public comment on data collection related to communication studies. No animal testing is involved.

FDA received a comment that made a series of complaints against the Agency unrelated to its notice for public comment. Accordingly, those comments are not addressed in this document.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 U.S.C. 393(d)(2)(D)	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Individual in-depth interviews	360	1	360	.75	270
General public focus group interviews	288	1	288	1.50	432
Intercept interviews: Central location	200	1	200	.25	50
Intercept interviews: Telephone [2]	2,000	1	2,000	.08	160
Self-administered surveys	2,400	1	2,400	.25	600
Gatekeeper reviews	300	1	300	.50	150
Omnibus surveys	1,200	1	1,200	.17	204
Total (general public)					1,866
Veterinarian/scientific expert focus group interviews	288	1	288	1.50	432
Total (overall)					2,298

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] These are brief interviews with callers to test message concepts and strategies following their call-in request to an FDA Center 1–800 number.

Dated: December 7, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31891 Filed 12–17–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Defense Advanced Research Projects Agency and Food and Drug Administration Expanding In Vivo Biomarker Detection Devices Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop cosponsored with the Defense Advanced Research Projects Agency (DARPA): Expanding In Vivo Biomarker Detection Devices Workshop.

The DARPA Defense Sciences Office and the FDA Center for Devices and Radiological Health (CDRH) are hosting a workshop to discuss current state-of-the-art and innovative research opportunities in the area of in vivo analytical devices capable of measuring biomarkers that characterize normal biological processes, pathologic