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June 21, 2004

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Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

**Subject: Docket No. 2004N-0166 Infant Feeding Practices Study II**

To Whom It May Concern:

Wyeth appreciates the opportunity to comment on FDA's upcoming Infant Feeding Practices Survey (IFPS) and commends FDA's effort to gain a better understanding of mothers' knowledge of infant nutrition and feeding, and their current feeding practices. In general, the study is designed well in that it captures a respondent's thinking and plans for infant feeding during pregnancy, then seeks to identify changes in this thinking and planning by assessing actual feeding practices over the first 12 months post partum. The information obtained from this comprehensive survey will be useful in identifying gaps in understanding about the importance of good nutrition during the first year, including the benefits of breast-feeding, help identify potential barriers to breastfeeding, and provide a basis upon which to improve education and communication strategies for better public health. We are especially pleased to have one point of emphasis be on the proper use of infant formula, and have concentrated our comments on this aspect.

Factual information is needed on how much influence, if any, infant formula labeling and advertising have on a woman's decision to use infant formula. Wyeth proposes adding questions that could provide important, unique data to address long standing disputes about labeling marketing and use of infant formula.

There is a belief that labeling and advertising of infant formula can influence a mother's choice to begin or continue to breast feed, however there are few data that indicate such an influence is true. Indeed, the Codex Committee on Food Labeling included in its Guidelines on Health Claims<sup>1</sup> a prohibition against such claims on infant formula, despite evidence from WHO<sup>2</sup> and others<sup>3</sup> that the impact of health claims on consumer purchase behavior is unclear. The IFPS collects information on sources of information about infant feeding, but does not categorize that information according to its importance. Specifically the IFPS could assess whether mothers read infant formula labels before they decide whether or not to breast-feed, and if so, how much of an influence the information on the labels was on their decision. We suggest below particular questions that, with slight additions or revisions, would capture this information. Similarly, given the controversy about the current breast-feeding awareness campaign, an assessment of the impact of the advertising campaign on a woman's decision making would be useful.

The comments below refer to specific, individual questions.

The first questions about breast-feeding occur in the section on the work environment. It seems more logical to identify earlier in the questionnaire when a woman first decides her choice of feeding method, followed by a question eliciting the primary influencers of her decision. From this point, the respondent could be referred to the next, appropriate module, based on choice of feeding method.

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In the Prenatal questionnaire, Q 28 is vague because it does not specify the time of feeding, and there may be different responses to this depending on the age of the baby. It also introduces a bias because mothers know they are supposed to answer that breast-feeding is best.

Only in Q29 is the timeframe defined at "first few weeks".

Q31 simply records exposures to public education or information about breastfeeding or formula, and does not assess subjective impact. The question is adequate to assess awareness of these sources of information. To assess impact, additional question(s) about how much impact the public communication or advertisements had on knowledge, decision-making and behavior should follow. This is a key point. It is often asserted that industry label claims and advertising are influencing a mother's decisions to stop breast-feeding or on the timing of weaning. The IFPS could directly address this issue by asking the mother to rate the influence of certain information on her decision-making.

Q32 only asks how strongly Mom agrees with the statement. It does not specify what "less" means. It does not specify what "good" is. Magnitude of agreement does not differentiate emotional commitment from understanding of scientific relationships, and it may be useful to differentiate between these reasons for response in order to refine educational campaigns.

At Q40 there could be some parallel questions about formula feeding, otherwise the concentration on breast-feeding could introduce respondent bias, leading the respondent to answer according to expectation. (The section is entitled infant feeding, but without some balance could be retitled breast-feeding.)

On the neonatal questionnaire at Q14 could contain responses that identify either the *breast-feeding promotion* or *infant formula labeling* or *infant formula advertising* as possible reasons a mother decided to not breast-feed. There is no response for the woman who made a choice to not breast feed for personal preference, who thought breast-feeding was inconvenient, or for women who wanted to place their careers ahead of breast-feeding. The closest response is "*had to go back to work*" where there is no response on "*wanted to go back to work*"; the latter has a lot of subservient reasons that could be explored. There is no response aimed at a mother's decision based on economics, which is especially important in the context of claimed health benefits of continued breast feeding and associated medical care cost reductions. Also, this question fails to score the responses according to importance. Perhaps Mom could be asked to identify the three most important reasons in a subsequent question.

In Module D (Breast-feeding), Q16 should include advertisements (and other media like direct mail, internet, physician brochures) for infant formula and formula labels as possible reasons that Mom feeds her baby formula. These should also be included in Q5 of Module B (Stopped Breastfeeding) as possible reasons to stop breastfeeding.

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In Module E (Infant Formula) there are several questions that ask about clarity of and compliance with the directions for preparation, feeding and storage of infant formula on the labels. Wyeth recommends expanding these questions to include other label components and claims. Questions should be added to determine whether mothers find the nutrition content and information on special attributes on infant formula labels (1) useful and (2) desirable. Arguments about food labeling (e.g. labeling of genetically modified foods) often revolve around the value of providing consumers information upon which they can base a choice. The IFPS survey could directly learn the value to the mother of required or optional labeling statements on formula. In particular it would be valuable to know if mothers understand health/label claims on formula in the proper context, e.g. one formula compared to other formulas, or if the statements require rewording to avoid inappropriate comparison of the formula to breast feeding, or unintended comparisons to other foods like cows milk or juice.

Finally, some questions should be added to Module E about mothers' perception or understanding of how safe infant formula powder is from a microbiological standpoint, and whether infant formula powder is sterile.

Once again, Wyeth appreciates the opportunity to comment on the Infant Feeding Practices survey, and hopes that FDA agrees to incorporate additional questions to address questions about the importance of labeling and advertising on infant formula.

Regards,

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## References

- 1 Codex Committee of Food Labeling, 32<sup>nd</sup> session  
<http://www.codexalimentarius.net/reports.asp>
2. Nutrition Labels and Health Claims on Foods: the Global regulatory environment, Dr Corinna Hawkes, WHO, Draft provided at the 32<sup>nd</sup> session of CCFL.
3. Marquart L. Wiemer KL. Jones JM. Jacob B. Whole grains **health claims** in the USA and other efforts to increase whole-grain consumption. *Proceedings of the Nutrition Society*. 62(1):151-60, 2003.