NATIONAL CONSUMERS LEAGUE
1701 K Street, NW, Suite 1200, Washington, DC 20006
PHONE (202) 835-3323 FAX (202) 835-0747 www.nclnet.org

February 27, 2006

BY ELECTRONIC MAIL
http://www.fda.gov/dockets/ecomments
Division of Dockets Management (HFA –305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

COMMENTS OF THE NATIONAL CONSUMERS LEAGUE
TO DOCKET NO. 2005N-0354
FOOD AND DRUG ADMINISTRATION
CONSUMER DIRECTED PROMOTION OF
REGULATED MEDICAL PRODUCTS

The National Consumers League (NCL) is a private, nonprofit advocacy group representing consumers on marketplace and workplace issues. We are the nation's oldest consumer organization. NCL provides government, businesses, and other organizations with the consumer's perspective on concerns including child labor, privacy, food safety, and healthcare, including medication information. Our mission is to protect and promote social and economic justice for consumers and workers in the United States and abroad.

NCL has long been interested in ensuring that consumers receive accurate and useful information about their healthcare, including information about the safe and effective use of prescription drugs. Direct to consumer advertising of prescription drugs (DTC), is part of a long-term systemic shift toward patient-centered care. With this shift, it is critical that consumers are able to assess risks and benefits of health care treatments, including prescription medications.

These comments will focus on the following: 1) the presentation of risks and benefits in current DTC promotion, 2) some suggested improvements for DTC, 3) other communications regarding prescription medications, including in – pharmacy communications and 4) FDA oversight.

I. Risk and benefit information in current DTC ads

DTC can be a useful tool for initiating and complementing patient/health care professional communication. Armed with balanced, clear information, consumers can initiate discussions with their physicians about the risks and benefits of, and alternatives to, prescription drugs, as well as discuss medical issues they may not otherwise.

A 2002 NCL survey of over 1000 adults showed that more than half of those who saw a DTC ad were motivated to take action - 31% decided to talk with their doctor about the medication at their next appointment, and 26% sought more information about the drug from various sources. Those who sought more information - from pharmacists, medical or drug reference books or a health Web site - wanted to know if the drug was right for them or a family member. In addition, the survey showed that consumers are wary of DTC advertising and cynical about the motives of pharmaceutical companies – more than half agreed that ads just help pharmaceutical companies sell their drugs, and nearly half think the ads are largely responsible for the increased cost of prescription drugs, and that they encourage people to ask for medications they do not need or cannot take.

DTC needs to do a better job of presenting balanced risk and benefit information, and not create unreasonable expectations or promote inappropriate use. We know that consumers are failing to take away important information health information after seeing, hearing, or reading DTC ads. While risk information is present in these ads, it may be difficult to comprehend due to the technical vocabulary and formats used, such as small type. In broadcast ads, risks may be missed by consumers when they are listed very quickly in one continuous segment and while contradictory visual images are shown. Confusion of risk information can affect consumers' perception of risk. We encourage the continuing study of the most effective way to present risk and benefit information to consumers.

II. Suggested improvements to DTC ads

FDA's current requirements and policies for prescription drug advertising and promotional labeling are ill-suited to communicating information to consumers. FDA should revise its regulations and policies to allow for more consumer-friendly information about the safe and effective use of prescription drugs that is clear and understandable to the <u>average</u> consumer.

NCL supports FDA's 2004 draft guidance recommending alternatives to the current brief summary common in most print ads. Because the brief summary is accompanying an advertisement, and a consumer must still obtain a prescription before receiving the medication (which when dispensed will be accompanied by more information on safe use and risks and benefits), NCL believes certain information can be deleted from the brief summary – including exhaustive risk information, dosage and administration. In this context, "less is more" – the emphasis in DTC ads should be on the most serious and common side effects.

NCL further believes that a standardized information panel, such as a "Rx Facts" box, much like the successful format now being used for "Nutrition Facts," "Supplement Facts," and

OTC "Drug Facts," would be a better way to communicate risks and benefits to consumers. Coupled with user-friendly language, and "adequate provision" for the consumer to obtain additional information from other sources, this approach would benefit consumers. We are encouraged that FDA seems to consider this type of standardized information panel as one option in the 2004 guidance. NCL is also pleased to see that some pharmaceutical companies are seeking consumer input to re-format the risk and benefit information in creative formats, such as Question and Answer and "Fast Fact" formats.

For DTC ads to truly educate and benefit consumers, they should not only contain understandable risk information, but also information on the drug's benefits. Many ads use vague, qualitative terms to describe benefits, for example "lower your number" for cholesterol drugs. The absence of actual benefit data may lead consumers to believe that a drug works better than it actually does. A "benefit box" with published data on the chance of various outcomes with and without the drug, should be considered for inclusion in DTC ads. Consumer perception of drug effectiveness could be improved with this type of information.

NCL would also welcome more educational content about disease and conditions in DTC ads. If consumers understand the role drug therapy plays in treating their disease or condition, they will have reasonable expectations of the drug's benefits.

In addition, we would encourage more disease awareness messages/communications (without the promotion of a specific drug). If we really want to improve public health, we should spend some of the billions of dollars spent on DTC on messages about disease awareness, health conditions, diet, exercise, and drug compliance, that are NOT product specific. For certain under diagnosed diseases and untreated conditions, such messages are conversation starters between patients and health care professionals. These communications should include evidence-based information, and direct consumers to reliable sources for more information.

III. Other messages/communications consumers receive about prescription medications

We know that consumers obtain information about the prescription drugs they take from many sources – from their physicians, pharmacists, drug package inserts, health plans, Internet, magazines, newspapers, and friends and family. Given this, FDA should consider how its policies can foster, rather than hinder the flow of communication from these alternative channels. Restrictions and disclosures that are necessary for sponsored DTC ads may not be appropriate for communications from health care professionals and pharmacies and may even interfere with consumer comprehension.

The amount and type of information required to accompany prescription drug communications should depend on the particular type of message. A "one size fits all" requirement is not appropriate. For example, sponsored messages that encourage patients to continue taking the drug therapy that has been prescribed and already dispensed are different from advertisements in the mass media and should be treated differently. These Compliance/persistence messages should not be considered "promotional" in this context.

In addition, customized messages delivered by a pharmacy with a drug being dispensed should also be treated differently. These messages are part of the practice of pharmacy, and the pharmacist is readily available to discuss the drug dispensed or adjunctive/alternative treatment with the patient.

FDA should follow the Department of Health and Human Services final privacy rule, which deems refill reminders and pharmacy-initiated communications to be part of a health care professional's treatment of a patient, not marketing. NCL would welcome further guidance from the FDA on in-pharmacy communications.

FDA needs to also remember that divisions of FDA-CDER should not operate in a vacuum. Patients do not understand the fine differences between advertising, promotional labeling, package insert, the drug monograph, and MedGuide, which are the responsibilities of different FDA-CDER offices. Information consumers receive with their medications must be coordinated, understandable, and not duplicative or inconsistent. NCL believe that the Consumer Medication Information, or CMI, should be the information vehicle of choice. Furthermore, FDA should develop a separate guidance for accompanying information requirements that apply within the pharmacy.

IV. FDA oversight

NCL believes FDA should be able to review all DTC ads before deployment. This would enable agency staff to revise material, if necessary, so misleading information does not reach consumers. In order to effectively and efficiently review ads in a timely matter, FDA will, of course, need the resources to provide sufficient review staff. If FDA is not able to review ads before deployment, and ads are later found to be misleading, the sponsors should be required to engage in corrective action to remedy the misrepresentation.

We'd also like to see consideration by the FDA of prolonging the period between drug approval and initiation of product promotion. In other words, a moratorium on advertising for certain drugs when there is the need to gather more safety information, and educate physicians. It has been suggested that FDA should even consider adding a "provisional" status for some new drugs. Such a status would allow for limited exposure of the product to appropriate patients, while there is additional post-approval safety data collection.

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In closing, NCL appreciates this opportunity to comment on this important issue.

Sincerely,

LINDA F. GOLODNER
President