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

Docket No. 2004D-0042

Comments of the National Consumers League
On FDA Draft Guidances To Improve
Health Communication To Consumers
Reopening of Comment Period

The National Consumers League is pleased to submit additional comments to the Food and Drug Administration (FDA) on the Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions, 69 Fed. Reg. 6308 (Feb. 10, 2004) and 69 Fed. Reg. 30945 (June 1, 2004). NCL previously submitted comments to this docket on May 4, 2004. However, given NCL's long commitment to increasing consumer access to accurate, useful medication information, we wish to supplement our previous remarks and comment upon certain submissions made to FDA.

- ?? As stated previously, NCL strongly and enthusiastically supports the reformatting of the "brief summary" to provide important risk and benefit information in a consistent, balanced format and in plain language. Above all, the brief summary must be useful for consumers. We are concerned about the number of comments that have voiced the view that pharmaceutical companies will be reluctant to use better, consumer-friendly brief summaries because of enforcement and liability issues. NCL urges FDA to do everything it can to resolve these competing priorities in favor of better, clearer information for consumers.

- ?? As stated previously, NCL believes that effective communication of risk to consumers is undermined by the technical, exhaustive recitations from a drug's full professional labeling. Consumers require clear, plain information about prescription drug safety and effectiveness. To this end, NCL continues to support consideration of the broadcast approach as a workable alternative for DTC print promotions, so long as the print promotion:

- is truthful and not misleading,
 - contains a plain, prominent statement of the risks associated with the drug; and
 - the advertiser has made adequate provision for the consumer to obtain information from other sources.
- ?? NCL encourages FDA to undertake the research into different brief summary formats that commentators have urged. We now know with the benefit of research that the typical brief summary does not work for consumers. We need similarly sound research into what alternatives would better aid consumer education and comprehension.
- ?? One format proven to be an effective communication tool for other FDA-regulated products is the Facts box. In furtherance of the goal of clearer, plainer communication of risk information, NCL continues to believe that FDA should consider a standardized information panel, such as an Rx Facts box. We note that a comment from the University of California San Francisco School of Pharmacy has considered this option in great detail, and similarly endorses an Rx Facts box approach. We urge FDA to give the Facts box information vehicle the serious consideration it deserves.
- ?? The National Association of Chain Drugstores (NACDS) has urged FDA to consider an exemption from brief summary requirements for those communications that a pharmacist disseminates to his or her patients. As we explained previously, the restrictions and disclosure requirements that are necessary for drug sponsors' DTC advertising may not be useful for communications from health care professionals, pharmacies, and health plans and may even interfere with consumer comprehension and patient care. NCL urges FDA to look especially at the NACDS proposal and the special challenges of in-pharmacy communications.
- ?? NCL asks that FDA issue a technical correction when it issues the final guidance. NCL supports the dissemination of information such as refill reminder letters, booklets, and brochures that allow consumers to get the most from the therapies their doctors have already prescribed. NCL understands, however, that FDA deems these types of communications to be "labeling" that, to be fully compliant, should include the full drug labeling intended for health care professionals. The distinction between "labeling" and "advertising" is a regulatory nuance that is irrelevant to consumers. NCL asks FDA to clarify that it will permit dissemination of the new, consumer-friendly brief summary or other similar document (such as the FDA approved patient labeling, if it exists) with any DTC promotion, whether "labeling" or "advertising."

Thank you for your ongoing efforts to improve consumer healthcare information and education.

Sincerely yours,

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