NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES



June 20, 2001

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

**Re: Issues Associated with the Intersection of 180-Day Generic Exclusivity and Pediatric Exclusivity – Docket No. 01N-0103**

To Whom it May Concern:

The National Association of Chain Drug Stores ("NACDS") is pleased to submit these comments to the FDA regarding the "intersection" of (a) the 180-day generic drug exclusivity ("Generic Exclusivity") granted by the 1984 Drug Price Competition and Patent Term Restoration Act, and (b) the 180-day pediatric exclusivity ("Pediatric Exclusivity") granted a brand name drug manufacturer under the 1997 Food and Drug Administration Modernization Act. FDA sought comments regarding whether these two exclusivity periods should run concurrently or consecutively. 66 Fed. Reg. 27983 (May 21, 2001). In order to encourage production of generic drugs, NACDS believes the exclusivity periods should run consecutively, with Generic Exclusivity following Pediatric Exclusivity.

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NACDS membership consists of almost 180 retail chain community pharmacy companies. Chain community pharmacy comprises the largest component of pharmacy practice with over more than 33,000 retail pharmacies, employing 94,000 pharmacists, with annual sales totaling over $400 billion. Chain operated community retail pharmacies fill over 60 percent of the approximately 3 billion prescriptions dispensed annually in the United States.

Generic Exclusivity was enacted to encourage generic manufacturers to challenge brand name manufacturer's patent claims, and thereby speed the market entry of the first generic competitor, without the fear of competition from other generic manufacturers who do not have to challenge the brand name manufacturers exclusivity. *See* 21 U.S.C. § 355(j)(B)(iv). Pediatric Exclusivity was enacted to encourage brand name manufacturers to conduct pediatric studies regarding their drugs. *See* 21 U.S.C. § 355a. NACDS supports both of these goals.

Consecutive running of the two exclusivity periods will encourage the pursuit of both goals. Brand name manufacturers that conduct pediatric studies will receive six months of exclusivity, after which the first generic manufacturer will receive six months of protection from other generic manufacturers.

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In contrast, concurrent running of the two exclusivity periods would eliminate the incentive to bring generic competition to the market. The protection from other generic competitors afforded by Generic Exclusivity would be useless if no generic manufacturer is allowed to market its product due to ongoing Pediatric Exclusivity.

FDA should not interpret the exclusivity periods in a way that reduces the incentives for generic drug competitors. Generic pharmaceuticals are a cost-effective way of providing prescription drug therapy. Pharmacists in community practice settings work with patients and physicians to maximize the use of lower-cost generics when they are available on the market. The savings from using generics are unmistakable. NACDS supports generic drug competition.

If the FDA interprets these exclusivities to run concurrently, then generic manufacturers lose most or all of the incentive to challenge brand name manufacturers' patents. The expense of successfully challenging a patent requires a significant investment that the generic company is entitled to recoup during the Generic Exclusivity period. This first generic manufacturer's challenge, if successful, also makes it possible for other generics to come to market after its 180-days of exclusivity expires. This helps to create price competition in the generic market, which benefits consumers, as well as public and private payors by lowering costs for generic drugs. The importance of this incentive to bring generics to market cannot be ignored. FDA recently stated that the number of generic drug products awarded Generic Exclusivity from only 3 during 1984-1996 to 28 during 1997-present.

We appreciate FDA's request for comments on these important issues. NACDS asks that you contact John M. Coster, Ph.D., R.Ph., Vice President of Federal and State Programs at 703-549-3001 X126 for further information. Thank you.

Sincerely,

S. Lawrence Kocot
Senior Vice President and General Counsel

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