Byron Chemical Company, Inc.
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June 1, 2000 5629 '00 JUN -2 A9:27
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DOCKETS MANAGEMENT BRANCH (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Gentlemen:

RE: [DOCKET NO. 00N-1266]
REPORT TO CONGRESS ON PEDIATRIC EXCLUSIVITY;
REQUEST FOR COMMENTS (FR 5/5/00, Vol. 65, No. 88)

Issue 1: The effectiveness of the program in improving information about important pediatric uses for approved drugs;

Comment: The program cannot succeed in improving information about pediatric uses unless the results of the pediatric studies are required to be reflected in the drug's labeling.

Suggestion: Require drug labeling revision, reflective of pediatric results, subsequent to FDA's review and suggestion for labeling.

Issue 2: The adequacy of the pediatric exclusivity incentive;

Comment: Considering 20 year patent life (GATT), Hatch/Waxman extensions and other mechanisms used to delay generic entry (e.g. orange book abuse, tablet/capsule switches, citizen petitions, P4 litigation), the windfall provided by an additional six months pediatric exclusivity, which extends across the board for all marketed products, is not only more than adequate, but excessive and inappropriate, when weighed against the potential benefits and the number of products which are the subject of potential pediatric exclusivity.

Suggestion: Pediatric exclusivity (at best) should be granted and applicable ONLY to the specific dosage and marketed product for which pediatric use is recommended and which results in a positive labeling revision for pediatric use.

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Issue 3: The economic impact of the pediatric exclusivity program on taxpayers and consumers and the impact of the lack of lower cost generic drugs on patients, including on lower income patients;

Comment: The six month pediatric extension is clearly a financial burden to taxpayers, consumers, the government and the elderly, considering these six additional months will cost the public an average of 50% more than if generics entered the market six months earlier.

Suggestion: Use a tax incentive – equal to the cost of financing the studies, instead of subjecting the consumer and the government to higher prices for a longer period of time through extended exclusivity. There is no reason for a reward other than recovering the expenses associated with the pediatric studies. Children are part of the general population and deserve the same consideration. Rewards (e.g. Waxman/Hatch) are already in place in terms of monopoly extensions and marketed drugs are already benefiting from existing sales and profits.

Issue 4: Suggestions and Modifications

1. Establish a rational criteria for selecting drugs intended to be the subject of pediatric studies, considering its therapeutic category, benefit vs. risk and other alternative drugs already available. The assessment should truly be based on a health need for children and not on the broad range of drugs which are primarily focused on extending already existing monopolies. Drug selection and limitation is extremely important and should be considered carefully for children.

2. Finance the pediatric studies through tax incentives, not through exclusivity/patent extensions, which are far more costly to the consumer and to the government, than are the studies themselves.

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3. The concept of rewarding pediatric studies by extending monopolies through exclusivity is absolute discrimination against children. They are entitled to the same rights and consideration as every other potential consumer, without subjecting the balance of the population to high costs for a longer period of time, having been denied a generic during the pediatric exclusivity period. Children should not be designated as a population segment who benefits only from a drug if there is a substantial monopoly reward. It is not only a poor precedence for segmenting the population, but leaves the door wide open for further segmenting by later requesting exclusivity periods for geriatrics and others.

We appreciate your time in reviewing these comments and taking them under consideration.

Sincerely,

BYRON CHEMICAL COMPANY, INC.

Lc

Laura Candela

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