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Commissioner

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
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Re: 21 CFR Part 314 – RIN 0910-AC48
Docket N0. 02N-0417]
"Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not be Infringed"

To Whom It May Concern:

The New York State Department of Health has reviewed the proposed changes to the regulations implementing the Hatch-Waxman law regarding approval of generic drugs, published in the October 24, 2002, Federal Register.

We are in support of the proposed rules, and share the objective of attempting to assure greater and more predictable access to safe, effective and lower cost generic drugs. The new rules are consistent with the New York State Medicaid program's efforts to enhance the use of generic drugs through the recent Mandatory Generic legislation. The following comments are provided regarding the new rules:

- Clarification of regulations to describe the types of patents that must and must not be listed in the Orange Book (section 314.53(b)): The proposal states that information on patents claiming packaging, patents claiming metabolites, and patents claiming intermediates must not be submitted to the FDA. We recommend implementation of these changes in order to prevent the delay of appropriate generic drugs entities from entering the marketplace.

- Requirement of submission of a Patent Declaration by a person submitting an NDA, amendment to an NDA, or NDA supplement (section 314.53 (c)(2) (i)): We believe the use of the proposed patent declaration will ensure that

02N-0417 C 31

appropriate patents are listed and will preclude any need for the FDA to decide patent issues, issues which the FDA is not readily capable of dealing with due to lack of patent expertise, resources, and any statutory mandate to scrutinize patent listings. We recommend implementation of this proposal to prompt NDA applicants and holders to provide only appropriate patent information in their patent declarations that they can verify. The proposal will assist the FDA in assessing patent infringements, thereby expediting the approval of ANDAs for generic products.

- The number of times an applicant's approval date may be delayed for a 30-month period (sections 314.94(a) and 314.52(a)): Under these new regulations, multiple, 30-month stays per ANDA or 505(b)(2) application would no longer be possible. Currently, the Hatch-Waxman amendments create the opportunity for multiple 30-month stays and the number of 30-month stays per product has been increasing, particularly for a limited number of "blockbuster" drugs. We strongly recommend that this proposal be adopted to enhance the earlier availability of less expensive generic drugs. This will assist New York State programs (e.g. Medicaid, the Elderly Pharmaceutical Insurance Coverage [EPIC] Program and the AIDS Drug Assistance Program [ADAP]) to obtain less costly drugs for their clients.

The proposed changes will result in more timely access to generics for all consumers, and will result in cost savings for New York State pharmacy programs. We enthusiastically support this proposal.

Sincerely,

Antonia C. Novello, M.D., M.P.H., Dr. P.H.
Commissioner of Health