

NAPM



NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS

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November 16, 2000

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

Re: Paragraph IV Patent Certifications
(Docket No. 00P-1556)

Dear Food and Drug Administration:

The National Association of Pharmaceutical Manufacturers (NAPM) submits this comment in response to the October 4, 2000 citizen petition regarding the disclosure of information about Paragraph IV patent certifications. NAPM is a national, not-for-profit trade association representing manufacturers and distributors of generic drugs, as well as suppliers of bulk pharmaceutical chemicals and other goods and services to the U.S. generic drug industry.

Disclosure of Date on Which First Paragraph IV ANDA Was Received

The petition requests that FDA disclose the date on which the first Paragraph IV abbreviated new drug application (ANDA) was received in connection with any reference listed drug. While NAPM supports FDA efforts to maintain confidentiality with regards the identity of an ANDA applicant, NAPM agrees with the petitioner that release of the filing date does not jeopardize this confidentiality. Disclosure of the date the ANDA was received would not violate confidentiality requirements contained in 21 C.F.R. § 314.430 because neither the applicant's identity nor any details about the drug are implicated.

Disclosure of this date on the FDA-Paragraph IV website makes sense. FDA currently posts a list of drug products for which a Paragraph IV ANDA has been received. On the website, FDA states both that it is not disclosing when the ANDA was received and that the listings are to be updated monthly. As noted by the petitioner, by monitoring the website one can easily deduce the approximate timing of a Paragraph IV ANDA filing. For FDA to take the next step of providing the actual filing date is logical and promotes efficiency. To an ANDA holder, knowing whether it is the first-filed Paragraph IV ANDA or not allows for more precise and productive

00P-1556

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Letter to Dockets Management Branch
November 16, 2000
Page 2

decisionmaking. Such knowledge would work to benefit all who rely on the availability of generic pharmaceuticals.

Disclosure to Applicant Whether It Was the First to File

NAPM supports FDA also disclosing to an inquiring applicant whether it was the first to file a Paragraph IV ANDA. Such a disclosure would not require FDA to divulge the name of other applicants or other confidential information. In fact, all that would be required would be for FDA to respond in the affirmative or the negative. As discussed above, this common sense disclosure would enable ANDA holders to make prudent business plans with regards to manufacturing and marketing.

Disclosure of the Patent Number to Which a Paragraph IV Certification Is Made

The specific patent to which a Paragraph IV certification has been filed should be disclosed by FDA. Oftentimes multiple Orange Book patents are implicated by a Paragraph IV ANDA, and there should be disclosure as to which specific patent is the subject of the certification. NAPM agrees that posting this information on the Paragraph IV website, along with making it available to phone call inquiries, makes sense. Once again, proprietary information would not be disclosed. The only outcome of this disclosure, as with the other requested disclosures, would be that ANDA holders would be more informed when business planning.

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NAPM believes the 180 day exclusivity “reward” is an important incentive for generic drug manufacturers to engage in necessary research and development, as well as to defend against costly patent infringement litigation that is often necessary if a generic drug product is to be marketed before the expiration of a patent listed in the Orange Book. The relief sought by the petition would enhance the value of this “reward” by reducing uncertainty and providing for more informed business planning. Consumers, in turn, would benefit by the reduction in market delays and therefore greater and quicker access to affordable generic drugs. The actions requested in this petition are common sense reforms that would not place additional burdens on FDA. Importantly, the actions would also not involve the disclosure of confidential information.

Letter to Dockets Management Branch
November 16, 2000
Page 3

The members of NAPM thank the agency for its consideration of this comment.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert S. Milanese", with a date "11/16" written to the right of the signature.

Robert S. Milanese
President

/lws

