DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

SENT VIA E-MAIL

Michelle Bonomi
Senior Vice President, Regulatory Affairs
Par Pharmaceutical Companies, Inc.
One Ram Ridge Road
Spring Valley, NY 10977

Dear Ms. Bonomi:

This is the agency's response to your e-mail of January 29, 2014. That e-mail was sent as a follow-up to a January 24 meeting of representatives of Par and the agency. The meeting was held at the agency's request to discuss Par's practice of sending premature notifications of paragraph IV certifications in violation of section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and 21 CFR 314.95(b).

At the meeting, the agency made its position clear: the agency considers notices sent before receipt of an abbreviated new drug application (ANDA) to be premature and therefore invalid and requested that Par stop sending paragraph IV notifications prior to an ANDA being received. The agency noted that in addition to being a violation of the statute and regulations, any notice sent before an ANDA is received for filing is a source of confusion to the recipients, and requires the agency and, at times, the courts to sort out the confusion created by this practice. Among other things, this diverts agency and judicial resources from more productive activities. The agency opined that use of this device, often contrived by the submission of an application and the easy use of the amendment procedure (with a notice of paragraph IV certification accompanying the amendment), appears to be a misguided effort to achieve some perceived advantage for 180-day exclusivity purposes. FDA informed Par that no such advantage exists and that premature notices of the type Par has submitted violate the statute and the explicit requirements of the regulations and have no legal effect for 180-day exclusivity or any other purposes. Our position has not changed.

At the January 24 meeting, Par informed the Agency that it intended to continue its violative practice. Par's explanation for its practice was that Par's premature notification was based on a "literal" reading of section 505(j)(2)(B)(ii)(II) of the FD&C Act and 21 CFR 314.95(d), and was done "in an abundance of caution" in light of *Purepac Pharmaceutical Corporation v. Thompson*, 354 F.3d 877 (D.C.Cir. 2004). Par acknowledged that its notice did not comply with 21 CFR 314.95(c) but did not explain why this provision did not apply to Par. In response to questioning by the agency, Par also acknowledged that it was aware of the court's decision in *SB Pharmco Puerto Rico, Inc. v. Mutual Pharmaceutical Co.*, 552 F. Supp. 2d 500 (E.D.Pa.), *appeal dismissed*, 2008 App. LEXIS 27672 (Fed. Cir. 2008). In disapproving of the practice of premature notification in conjunction with amendments submitted before an ANDA is received for filing, that court said:

> If an ANDA applicant could send Paragraph IV notice when amending an ANDA that has not yet been accepted as received, the applicant could accelerate the timing provisions and litigation process well beyond the framework that Congress intended.

Id., at 510. It is noted that the *SB Pharmco* decision was an interpretation of the relevant provisions of the statute as they now exist, while the *Purepac* case was based on the FD&C Act prior to the significant amendments to the paragraph IV certification and notification requirements passed in December of 2003. Moreover, premature notification was not before the court in *Purepac*; in that case, both ANDAs had been received many months before the events at issue. In contrast, the practice of premature notification in conjunction with an amendment submitted prior to FDA's receipt of an ANDA for filing was squarely before the court in *SB Pharmco*.

At the January 24 meeting, Par offered to include in its paragraph IV notifications language that Par believes could help reduce confusion, and distributed an already prepared draft of such language. FDA deferred specific comment on the language provided at that time. Par offered to share with FDA revised language, which you forwarded to us in your e-mail of January 29. It reads as follows:

(b) (4)

In implementing 21 U.S.C. 355(j)(2)(B), the regulations at 21 CFR 314.95(c) state what must be included in a notice of certification. This regulation at 21 CFR 314.95(c)(1) sets forth the requirement that the notice include "a statement that FDA has received an [ANDA] submitted by the applicant." FDA's regulation at 21 CFR 314.101(b)(1) defines the term "received." It states that "An [ANDA] will be reviewed after it is submitted to determine whether the [ANDA] may be received. Receipt of an [ANDA] means that FDA has made a threshold determination that the [ANDA] is sufficiently complete to permit a substantive review." As FDA has conveyed to Par both in writing and at the January 24 meeting, and regardless of the additional language Par chooses to include, a notice provided before an ANDA is received for filing cannot comply with this regulatory requirement and therefore is invalid on its face. This regulation does not,

however, proscribe inclusion of any additional information or statements. Indeed, the regulation plainly states that the notice "shall include, but not be limited to" the required information. The agency, therefore, has no objections to the inclusion of the language above. We do note, however, that FDA does not agree that the first sentence of your proposed additional language is true, complete, or accurate in light of our reading of the statute and regulations as a whole and the court's finding in *SB Pharmco*.

Sincerely yours,

{See appended electronic signature page}

Kathleen Uhl, M.D.
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KATHLEEN UHL
03/11/2014