Office of Review Management

Granting Waivers Under 21 CFR 314.90 for Postmarketing Safety Reporting Requirements Under 21 CFR 314.80

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PURPOSE

This MAPP explains CDER policy handling industry requests for waivers of postmarketing safety reporting requirements in 21 CFR part 314. These requests will be handled by CDER's Office of Post-Marketing Drug Risk Assessment (OPDRA) according to procedures outlined below.

BACKGROUND

In May 1997, the International Conference on Harmonisation (ICH) guidance entitled *E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drug*s published in the *Federal Register*. In August 1997, the Agency published a guidance for industry, entitled *Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products; Clarification of What to Report*. Both of these documents outline various changes that CDER believes will provide better postmarketing safety reporting and make better use of our postmarketing surveillance resources. The ICH E2C guidance recommends using a new format and content for postmarketing periodic safety reports. The *Clarification of What To Report* guidance specifically encourages industry to request waivers of the requirement in § 314.80(c)(2)(ii)(b) to submit in periodic safety reports individual case safety reports of nonserious, labeled suspected adverse drug reactions (SADRs). We prefer that industry submit them in tabular form. The waivers may be requested under § 314.90. We currently are using notice-and-comment rulemaking to incorporate these changes into our postmarketing safety reporting regulations.

In the meantime, many companies have expressed an interest in following some of the provisions of the two guidances, rather than the present reporting requirements in § 314.80. They have requested waivers, under § 314.90, to allow them to do so, and those requests usually have been granted.

As the number of waiver requests received has grown, it has become apparent that CDER needs a policy for handling these requests under § 314.90 and developing responses to them. This policy addresses that need.

REFERENCES

- Guidance for industry, *Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products; Clarification of What to Report*
- § 314.80
- § 314.90
- ICH *E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drug*s

POLICY

- All requests for waivers, under § 314.90, for any requirement under § 314.80 (postmarketing reporting of adverse drug experiences) should be addressed to the Director (or Acting Director) of the Office of Post-Marketing Drug Risk Assessment (OPDRA); a copy of the waiver request should be submitted as an amendment to the specific NDA(s).

- Upon receipt by the Director/Acting Director of OPDRA, requests will be logged into the § 314.80 waiver tracking system.

- *Routine* requests (e.g., waiver for reporting of individual case safety reports of nonserious, labeled SADRs or a waiver asking for permission to follow the ICH E2C format for periodic safety reports) will be handled by the Director/Acting Director of OPDRA.

- For *unique* waiver requests, the Director/Acting Director of OPDRA will consult with the OPDRA division and the ODE division responsible for the product before issuing a decision on the waiver.

- Copies of waiver request response letters issued by the Director (or Acting Director) of OPDRA will be sent to the directors of the OPDRA division, the

ODE Office, and the ODE review division responsible for the postmarketing oversight of the product. In addition, a copy of the response will be forwarded to the supervisory project manager of the ODE division responsible for the product and to the product's NDA(s) for archival filing.

- To help maintain consistency in our approach to these waivers and recognizing that many such requests involve products in many ODE divisions, all waivers under § 314.90 regarding § 314.80 requirements must be signed by the Director (or Acting Director) of OPDRA, the Deputy Center Director (Review Management), or the Center Director. An ODE division or office director should ***not*** sign such waivers.

- If the request involves a product that is not yet approved (i.e., it involves a request to alter the reporting requirements for a product that is just about to be approved), that request should be handled as one of the *unique* requests outlined previously.

- If members of an ODE or OPDRA division get inquiries about these kinds of waivers, please refer them to the Director (or Acting Director) of OPDRA.

EFFECTIVE DATE

This MAPP is effective on the date of publication.