WISCONSIN LEGISLATIVE COUNCIL
RULES CLEARINGHOUSE

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CLEARINGHOUSE RULE 15-068

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated December 2014.]

1. Statutory Authority

It is unclear why s. 961.20, Stats., is cited in the "Statutes Interpreted" section. Section 961.20, Stats., relates to Schedule IV substances, but the proposed rule exempts naloxegol from being classified as a Schedule II substance under s. 961.16, Stats. The board should review the citation to s. 961.20, Stats., to determine whether this citation is accurate. In either case, s. 961.16, Stats., should be listed as a statute that is being interpreted.

4. Adequacy of References to Related Statutes, Rules and Forms

It appears that 21 C.F.R. s. 1308.12 (b) (1) is the federal rule that was used as authority to promulgate this proposed rule. If so, this federal administrative rule should be referenced in the rule summary's section entitled, "Related statute or rule".

5. Clarity, Grammar, Punctuation and Use of Plain Language

a. The rule summary's section entitled, "Explanation of agency authority", appears to be a direct quote from s. 961.11 (4), Stats. If so, this section should be amended to clarify that it is quoting a statute. For example, the statute should be cited as s. 961.11 (4), Stats., and quotation marks should be placed around the quoted text. Preferably, the section would provide a plain language explanation of the pertinent parts of the statute.

b. The rule summary's section entitled, "Summary of, and comparison with, existing or proposed federal regulation", includes a summary of federal action to remove naloxegol from

being listed as a Schedule II substance under the federal Controlled Substances Act. However, this section does not include a discussion on how the proposed rule compares with federal law. Also, it would be helpful to provide citations to the applicable federal code referenced and the Federal Register where this final rule order was published (i.e., 80 F.R. 3468).

c. The rule summary's section entitled, "Plain language analysis", should begin with an analysis of what the proposed rule does and then continue with the background of the history of the Affirmative Action order.

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

   Comment Attached YES ☑ NO ☐

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

   Comment Attached YES ☐ NO ☑

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

   Comment Attached YES ☐ NO ☑

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]

   Comment Attached YES ☑ NO ☐

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

   Comment Attached YES ☑ NO ☐

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]

   Comment Attached YES ☐ NO ☑

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

   Comment Attached YES ☐ NO ☑

LCRC
FORM 2

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CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE **15-068**

AN ORDER to create CSB 2.39, relating to exclusion of naloxegol.

Submitted by **CONTROLLED SUBSTANCES BOARD**

09-03-2015 RECEIVED BY LEGISLATIVE COUNCIL.
10-02-2015 REPORT SENT TO AGENCY.

MSK:MS

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