From: **CDER Exclusivity Board** CDERExclusivityBoard@fda.hhs.gov
Subject: [EXTERNAL] RE: Exclusive rights related to ODD
Date: November 16, 2020 at 1:26 PM
To: Witkowski, Piotr [SUR] pwitkowski@surgery.bsd.uchicago.edu

CB

Good Afternoon,

Please forgive us for the delay in responding back to your email. Below are our responses:

1. Can the company waive its right to exclusivity?

As stated in FDA's regulation, a sponsor holding exclusive approval may consent to waive its orphan-drug exclusivity to permit approval of another marketing application. See 21 CFR 316.31(a)(3); see also section 527(b)(2) of the Federal Food, Drug and Cosmetic Act (FD&C Act); and the "Orange Book Preface" at https://urldefense.com/v3/__https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-pre__;!!OaZRxjSJGsACmqMyc8s!cmeoJilOs377FDvzc2Kv85wvfroJKh3No5UdPtgHJ8Zj__kqYYaxb1QOhNjpvDbvWOD0DiXP9H2ZACyT$
face.

2. If so, what is the procedure for that? Can it be done at the time of BLA submission or at the time of BLA approval or afterwards?

A sponsor that wants to waive its orphan-drug exclusivity should send a letter to the Office of Orphan Products Development (OOPD), with a copy to the relevant contact for the application in the Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER), stating its intent to waive exclusivity. The letter should state whether the sponsor intends to waive exclusivity for (1) all applications for the same drug for the same use or indication or (2) specific applications for the same drug for the same use or indication. The sponsor should send the letter to OOPD (with a copy to CDER or CBER) at the time of NDA or BLA approval or at any time afterwards when the sponsor decides it wants to waive exclusivity.

3. Can waiving exclusive right can be revoked, exclusive rights restored once waived?

If a sponsor initially waives its orphan-drug exclusivity, the sponsor can withdraw its waiver of orphan-drug exclusivity by sending a letter to OOPD (with a copy to CDER or CBER), so long as the timing is within the seven years from the time of approval of the NDA or BLA.

Sharnell

-----Original Message-----
From: Witkowski, Piotr [SUR] <pwitkowski@surgery.bsd.uchicago.edu>
Sent: Friday, September 4, 2020 5:10 PM
To: CDER Exclusivity Board <CDERExclusivityBoard@fda.hhs.gov>
Subject: Exclusive rights related to ODD

I have a question related to exclusive rights related to ODD.
I understand that once a company gets ODD for a new drug and then obtains BLA approval, the company can execute exclusive right to the specific drug marketing.
Can the company waive its right to exclusivity?
If so, what is the procedure for that? Can it be done at the time of BLA submission or at the time of BLA approval or afterwards? Can waving exclusive right can be revoked, exclusive rights restored once waived?
Thank you
PW