CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208798Orig1s000

ENVIRONMENTAL ASSESSMENT

NDA 208798 Addendum EA

Environmental analysis

The applicant has provided the following calculation

> *"The annual amount of Fp (kg/year [yr]) produced for direct use (i.e., A) was calculated based on Teva's forecasted need for the peak year of* (b) (4) *for* (b) (4) *the Mechanical MDPI inhaler* (b) (4) *The available doses (55 mcg, 113 mcg, and 232 mcg) for the Fp ingredient were multiplied by the annual projected number of units for the peak years. The quantities contained in each inhaler are multiplied by the annual projection number of units and converted from mg/yr to kg/yr as shown in the following equations: A =* (b) (4) *mg/dose x* (b) (4) *units/yr) +* (b) (4) *mg/dose x* (b) (4) *units/yr) +* (b) (4) *mg/dose x* (b) (4) *units/yr) +* (b) (4) *mg/dose x* (b) (4) *units/yr) +* (b) (4) *mg/dose x* (b) (4) *units/yr)] x* (b) (4) *kg/mcg =* (b) (4) *kg/year produced for direct use."*

(b) (4)

Almost everything is incorrect in this calculation

1. The values for "mg/dose" are actually "mg/unit."
2. The conversion factor of (b) (4) kg/mcg should be (b) (4) kg/mg

However the result is still (b) (4) kg/year. Therefore the calculated ppb is still (b) (4) ppb.

These levels are below 1 ppb at the point of entry into the aquatic environment. Pursuant to 21 CFR 25.31(b), the applicant claims a categorical exclusion from the requirement of an Environmental Assessment.

Reviewer's Assessment: **Acceptable.**

Craig Bertha

Digitally signed by Craig Bertha
Date: 1/24/2017 02:29:49PM
GUID: 50841a65000098a9383c817879a6a84d

Arthur Shaw

Digitally signed by Arthur Shaw
Date: 1/24/2017 02:21:43PM
GUID: 508da71e00029e07eb18aead84d4636d