Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Guevara LLC
d/b/a Franklin Package Store,

Respondent.

Docket No. C-13-1110
FDA Docket No. FDA-2013-H-0914

ALJ Ruling No. 2014-16

Date: December 6, 2013

RULING DENYING MOTION TO REOPEN DEFAULT JUDGMENT

I deny the motion of Respondent, Guevera, LLC d/b/a Franklin Package Store, requesting that I reopen the default judgment that I issued in this case on September 30, 2013.

I entered a default judgment against Respondent ordering that it pay a civil money penalty based on Respondent's failure to answer the administrative complaint that had been filed against it by the Center for Tobacco Products (CTP) of the Food and Drug Administration. On October 29, 2013, Respondent, through its counsel, moved that I vacate my default judgment and reopen the case. CTP now opposes Respondent's motion.

This case is governed by regulations at 21 C.F.R Part 17. Pursuant to these regulations, an administrative law judge may enter a default judgment against a party who has been served with an administrative complaint and who fails to file an answer timely. 21 C.F.R. § 17.11(a). In this case, Respondent does not deny

that CTP effected service upon her and that she failed to file an answer timely. Consequently, a default judgment is warranted under the regulations.

A default judgment may be reopened and vacated where a Respondent establishes "extraordinary circumstances" for failing to timely answer an administrative complaint. 21 C.F.R. § 17.11(c). The regulation does not define the term "extraordinary circumstances" but, clearly, that term must mean something more than a simple error or omission. An "extraordinary circumstance" would normally constitute some event or events beyond a Respondent's ability to control that acted to prevent the Respondent from filing timely. At the very least, the term would preclude reopening where ordinary negligence is the cause of a Respondent's failure to file an answer timely.

Here, Respondent asserts that an employee failed to tell her about the warning letter that CTP issued her. She concedes that someone at her business named Jose Batista signed the delivery receipt for the warning letter, but she argues that this individual was not qualified to receive mail, that he, apparently, did not understand the significance of the document that he signed for and, consequently, failed to tell her about it.

Even if that assertion is true, it would amount to no more than ordinary negligence by Respondent's staff, a situation that falls outside what is an "extraordinary circumstance." Respondent had the ability to control the circumstances. It could have trained its staff to recognize and to report important documents received through the mail and it could have instituted a system guaranteed to assure that important documents made it to Respondent's management. Thus, staff negligence or the inability of staff to comprehend the significance of the CTP warning letter is not a basis for reopening.

I would note, furthermore, that Respondent's arguments are based entirely on unsworn assertions by its counsel. Respondent has not offered an affidavit or sworn statement by any of its employees attesting to the facts that it now avers. I would not accept such unsworn contentions as a basis for reopening the default judgment even if they amounted to a persuasive argument for reopening, if true.

/s/

Steven T. Kessel
Administrative Law Judge