

BEFORE THE
OFFICE OF STATEWIDE HEALTH PLANNING AND DEVELOPMENT
STATE OF CALIFORNIA

In the Matter of the Penalty Issued to:

SUN PHARMACEUTICALS

Appellant.

OSHPD No. 20-014-Q4

PROPOSED DECISION

This matter was heard before Michelle Church-Reeves, Hearing Officer, Office of Statewide Health Planning and Development (“OSHPD”), State of California, on Thursday, July 23, 2020 beginning at 10:32 a.m.

Ty Christensen, Manager, Accounting and Reporting Systems Section, which oversees the Cost Transparency in Prescription Drugs (“CTRx”) Program, represented OSHPD.

Sun Pharmaceutical Industries, Inc., owner and distributor of Absorica LD, “Appellant,” was represented by Marc Wilenzick, Senior Counsel, Regulatory Law.

Both documentary and testamentary evidence was received. The matter was submitted for decision and the record was closed on Thursday, July 23, 2020 at 10:54 a.m.

PROCEDURAL FINDINGS

1. On Friday, April 3, 2020, OSHPD assessed a penalty against Appellant in the amount of \$64,000 for its delinquent New Drug Reports.

2. Appellant appealed the penalty by submitting a Request for Administrative Hearing form dated Friday, April 24, 2020 and received by the OSHPD Hearing Office on Monday, April 27, 2020.
3. Appellant submitted its appeals within the required thirty days from the date of the penalty notice.¹
4. The hearing was held electronically at the election of the Hearing Office. No party objected to an electronic hearing.
5. OSHPD submitted written exhibits to the Hearing Office and Appellant in advance of the hearing in a timely manner. Exhibits 1 through 14 were found to be authentic and relevant and admitted to the record.
6. Appellant did not submit written exhibits to the Hearing Office and OSHPD in advance of the hearing.

FACTUAL FINDINGS

1. Appellant was required under Health and Safety Code section 127681 to file four New Drug Reports for Absorica LD no later than 30 days after filing the New Drug Notices.² OSHPD calculated this deadline to be 11:59 p.m. on Saturday, February 29, 2020, and thus, OSHPD calculated penalties from Sunday, March 1, 2020, until Monday, March 16, 2020 when the reports were filed.
2. In accordance with Health and Safety Code section 127681, subsection (f), OSHPD assessed penalties in the amount of \$1,000 per day for 16 days for each of the four reports, resulting in a total penalty amount of \$64,000.³ These facts were substantiated both by oral statements made under oath by Mr. Christensen at the hearing and written exhibits.
3. Under Health and Safety Code section 127681, subsection (g), a penalty may “be reviewed on appeal, and the penalty may be reduced or waived for good cause.”

¹ Health & Saf. Code, § 127681(f).

² See also Cal. Code Regs., tit. 22, § 96077.

³ Health & Saf. Code, § 127681. See also Cal. Code Regs., tit. 22, § 96080.

4. Appellant submitted a written statement with its appeal and made oral statements of facts it believes show good cause why its reports were not submitted in a timely manner.

5. Appellant testified that this drug has been marketed since 2012, but this was deemed not therapeutically equivalent by the Federal Drug Administration. Accordingly, New Drug Notices and Reports were unexpectedly required. The New Drug Notices were filed timely, triggering the requirement to file the New Drug Report in 30 days, but the New Drug Reports were not filed timely.⁴ Appellant stated employees responsible for submitting the reports are no longer with the company, but at the time the responsible employees were Mr. Jae Lee and a consultant, Ms. Catherine Shattuck. Mr. Lee, with Ms. Shattuck's assistance, was developing the transparency program and managing and filing reports with multiple states on different timelines. As California's requirements are new, they were not fully incorporated into the Sun Pharmaceutical compliance process. The timelines, deadlines, and formats of reports have some variation between states. No reports were late prior to, or since, this group of New Drug Reports. OSHPD believed the reports were due by Saturday, February 29, 2020, and Ms. Shattuck and Mr. Lee did not submit the reports by this time. Appellant expressed it was a one-time mistake that they deeply regret. Appellant is committed to ensuring all reports are submitted on time or early. Appellant stated that the program has continued to grow, and a larger team is now led by Lindsey Pickarell. These facts were substantiated by oral statements made under oath by Mr. Wilenzick at the hearing.

6. OSHPD further testified that Sun Pharmaceuticals not only has a history of filing reports prior to and since this incident on time, but that Sun Pharmaceuticals has the distinction of being the first manufacturer to register with California and has made efforts to comply with all laws and regulations.

7. The initial statements of both parties were not rebutted.

8. OSHPD's representative confirmed that Appellant does have a history of filing required reports on time.

//

⁴ Health & Saf. Code, §127681.

DISCUSSION AND LEGAL CONCLUSIONS

1. The issue here is whether Appellant had good cause, as required by Health and Safety Code section 127681, for failing to file the New Drug Reports for Sun Pharmaceutical Industries, Inc. by February 29, 2020 and whether the penalty should be waived in whole or in part.

2. In *Waters v. Superior Court*, the California Supreme Court stated that, “good cause may be equated to a good reason for a party’s failure to perform that specific requirement from which he seeks to be excused.”⁵ Good cause must be directly related to the specific legal requirement which the party failed to perform and should be outside the reasonable control of the party.⁶

Good cause is sometimes defined as circumstances beyond the party’s control, and not related to the party’s own negligent act or failure to act. On an individual basis, courts and administrative bodies have often found that hospitalization, incapacitation, accident involvement, or loss or unavailability of records may constitute good cause.⁷ However, good cause is not limited to the listed reasons. In civil actions, a mistake can constitute good cause under some circumstances. This excusable neglect must be objectively honest and subjectively reasonable.⁸

3. The substantiated facts demonstrate a robust record of compliance from the time that Appellant registered with OSHPD’s CTRx program through most of their notice and report filings. Appellant even filed the New Drug Notice for this drug in a timely manner, clearly demonstrating a good faith effort to comply with the statutes and regulations. There are no substantiated facts which address whether Appellant’s responsible party believed filing the New Drug Notice was the same as the New Drug Report or whether Appellant simply missed the

⁵ *Waters v. Super. Ct. of Los Angeles County* (1962) 58 Cal2d 885, 893 (hereafter *Waters*).

⁶ *Waters, supra*, 58 Cal.2d 885,893 and Secretary of State, “Good Cause” Reasons for Waiving Late Campaign & Lobbying Filing Fees <https://www.sos.ca.gov/campaign-lobbying/good-cause-reasons-waiving-late-campaign-lobbying-filing-fees/> [as of December 4, 2019].

⁷ Fair Political Practices Commission, Guidelines for Waiving Late Fines (Nov. 2017) <http://www.fppc.ca.gov/content/dam/fppc/NS-Documents/TAD/FilingOfficer/700FO-Folder/Late%20Fine%20Guidelines.pdf> [as of December 4, 2019]. See also *Waters, supra*, 58 Cal.2d 885, 893.

⁸ Black’s Law Dict. (8th ed. 2004), p. 1601. See also Code Civ. Pro., §473.

deadline due to a mistake in calculating the due date. Appellant simply pleads a mistake which they are committed to ensuring does not happen again. Substantial actions have supported this commitment, both in the hiring of additional staff and the submittal of all other reports in a timely manner. These actions support the credible statements made by Appellant under oath at the hearing. It is clear the late filing was an objectively honest mistake and not willful or intentional, but it is difficult to ascertain whether the mistake was subjectively reasonable as we do not have the full facts from Appellant's primary responsible party, Mr. Lee. It is clear however that, as Appellant emphasized, a single mistake by Mr. Lee resulted in the group of four reports being late. The substantiated facts also show that this group of reports was for the same drug in differing dosage amounts, making the reports more similar than many other penalty assessments. While OSHPD was statutorily obligated to assess penalties for each report due to the separate National Drug Codes, the nature of the drugs makes it reasonable to group them for purposes of reducing the penalty.

4. Additionally, OSHPD calculated the deadline for the reports as Saturday, February 29, 2020 in accordance with Health & Safety Code section 127681(b). However, per Government Code section 6707, if the "last day for filing any instrument or other document with a state agency falls upon a Saturday," the document may be filed the next business day. Thus, the reports were legally due prior to 11:59 p.m. PST on Monday, March 2, 2020. This reduces the days the group of reports was late to 14 days.

5. Finally, Appellant's substantiated record of compliance and effort to work with OSHPD to meet the statutory intent demonstrates good faith and further supports Appellant's testimony that this was a one-time mistake which will not be repeated.

6. Therefore, Appellant met the burden of showing good cause for reduction of the penalty assessed. Treating the group of reports as one penalty and adjusting the penalty to begin accruing on the correct deadline reduces the penalty amount to \$14,000.

//
//
//

PROPOSED ORDER

The assessed penalty is waived in part, \$14,000 of the assessed penalty is upheld.

Dated: November 18, 2020

//original signed//

MICHELLE CHURCH-REEVES
Attorney, Hearing Officer
Office of Statewide Health Planning and
Development


DECISION

Pursuant to California Code of Regulations, Title 22, Section 96087, after due consideration of the record, the Proposed Decision is:

Accepted

Rejected

Dated: 11/30/2020

 (for Marko)
MARKO MIJIC
Acting Director
Office of Statewide Health Planning and
Development