DEPARTMENT OF FINANCIAL SERVICES
OFFICE OF PHARMACY BENEFITS
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In the matter of

Cipla USA, Inc.
Investigation No. 202010I-7

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CLOSEOUT AGREEMENT

This Closeout Agreement ("Agreement") is made and entered into by and among the New York State Department of Financial Services, with a mailing address of One Commerce Plaza, Albany, NY 12257 (the "Department"); and Cipla USA, Inc., with a mailing address of 10 Independent Blvd., Suite 300, Warren, NJ 07059 ("Cipla") The Department and Cipla are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

Statement of Facts:

1. Cipla Limited is a global pharmaceutical company. Cipla USA Inc. is a US subsidiary of Cipla Limited, and is based in Warren, New Jersey. Cipla USA Inc. produces and manufactures a variety of pharmaceutical drugs, and sells, or offers for sale, such drugs within the State of New York.
2. On April 3, 2020, Cipla made public a new product known as Budesonide 0.5mg/2ml inhalation, NDC 69097-0319-53 (box of 30 unit dose packages; total 60 ml) (hereinafter the "Drug"), which Drug is being offered for sale within the State of New York and has been paid for and is contemplated to be paid for in the future by insurance policies and contracts regulated by the Department.

3. On April 3, 2020, as is customary in the pharmaceutical industry, Cipla provided the wholesale acquisition cost ("WAC") for the Drug and other information to six data publishers, sometimes referred to as drug compendia—First Databank, IBM Watson Health, Medi-Span, ScriptPro, Gold Standard and Cerner. Of them, First Databank requires the WAC to be directly entered on its online portal (against the field representing WAC). The remaining data publishers require the WAC and other product details to be submitted in an Excel spreadsheet attached to an email.
4. Specifically, on April 3, 2020, an administrative associate from Cipla's Marketing & Sales Administration reported the price of the Drug as $279.14 and the launch date as April 3, 2020 to First Databank, the data publisher that requires the information to be entered online.
5. As for the email to the other five data publishers—IBM Watson Health, Medi-Span, ScriptPro, Gold Standard, and Cerner—when the associate had compiled the excel spreadsheet, instead of putting the price of the Drug as $279.14, they inadvertently keyed in $19.25; the associate also inadvertently keyed in "3/21/19" as the launch date for the Drug. The excel spreadsheet with the incorrect information was then emailed to all five of the compendia.
6. On April 24, 2020, Cipla discovered the discrepancies in the WAC and launch date reported to First Databank and that to the other data publishers. After further investigation, Cipla discovered that the errors were attributable to the associate who had entered an incorrect WAC and launch date on the spreadsheet that was sent to five of the data publishers (hereinafter the "Clerical Error").
7. On April 27, 2020, as directed by Cipla management, the associate wrote to the five compendia notifying them of the mistake in reporting the drug price and launch date and requesting that

the data publishers update the price to the correct price and launch date, and requesting immediate correction of the WAC to $279.14 effective from April 3, 2020. The associate further informed the publishers that this was a price correction (not a price increase).

8. However, Cipla recognized that one of the data publishers—Medi-Span—despite confirming the appropriate correction of the WAC as requested, updated an incorrect effective date of April 3, 2019. Additionally, DFS identified another database known as RED BOOK—which is produced by Micromedex—also reported an incorrect launch date of March 21, 2019 and published the correction as an increase.

9. Accordingly, the Clerical Error resulted in the appearance of a drastic price increase of the Drug as reported on certain databases including RED BOOK and Medi-Span, which appeared to show that the Drug price was increased on April 3, 2020, by 1350.1% from $19.25 to $279.14.

10. The apparent spike remained reported on these two databases throughout 2020 and were observed by the Department's Office of Pharmacy Benefits, which prompted the Department's investigations into the Drug price spike.

11. On January 20, 2021, the Department sent Cipla a request for a written statement pursuant to New York Insurance Law Section 111 concerning the significant drug price increase of the Drug, which appeared to have increased in price by over 1350% in the midst of the first wave of COVID-19 cases in the U.S. and on the heels of an announcement of international clinical trials for its use to treat COVID-19 patients (the "January 20, 2021 Demand Letter").

12. The January 20, 2021 Demand Letter stated that the Department had received information that on or about April 3, 2020, Cipla increased the price for the Drug by an amount that exceeded

fifty percent over the prior calendar year, that it has been sold or is being offered for sale within the State of New York, and that the Department was not aware of any pricing factors that would warrant such an increase in the price of the Drug, and accordingly it was determined that it is in the public interest that an investigation be made (the "Investigation").

13. On January 25, 2021, in compliance with Insurance Law Section 111 Cipla sent a response to the January 20, 2021 Demand Letter explaining that the perceived price increase of the Drug was due to the Clerical Error. Cipla further represented that there had never been a price increase of the Drug and that the Drug's intended price had always remained the same. Cipla also submitted documentation to corroborate these statements.

14. Cipla further acknowledged that, while it had attempted to promptly correct the errors in the reported price with the data publishers, one of the publishers-Medi-Span, despite confirming appropriate correction of the WAC as requested, updated an incorrect effective date of April 3, 2019.

15. This error had come to the attention of Cipla in response to the investigation and Cipla affirmed that it would request a correction to that date to read April 3, 2020.

16. The Department reviewed the representations, documents, and emails provided to the Department by Cipla and the Cipla legal team agreed to an interview. As part of the investigation, the Department held a conference call on January 26, 2020 with Cipla, in which Cipla representatives further explained the facts and circumstances around the perceived spike in the Drug price and further confirmed that the incorrect reported price had been corrected, was never communicated to consumers or downstream market participants, and never caused any harm to consumers.

17. The Department also concluded that in addition to the Medi-Span listing Cipla had noted the information listed on the RED BOOK continued to indicate the drug was launched in 2019 at a price of $19.25 and that the price action in April 2020 was an increase effective on April 3, 2020 to a price of $279.14, not a launch of the drug. This meant that while the price was appropriately reflected on the Red Book, the price history was incorrect and reflected pricing at levels that never existed for a period before the Drug was even introduced to the market.
18. On April 12, 2021 the Department sent Cipla a second request for an additional written statement pursuant to New York Insurance Law §111 concerning the Drug price increase ("Additional Information Demand"), requesting further information on the incorrectly reported Drug price; requesting information regarding the status of the correction submitted to Medi-Span with regard to the Drug's effective date; requesting additional information regarding how Cipla will improve its internal control to ensure inadvertent mistakes like this do not occur in the future; and requesting an explanation as to why the RED BOOK database still shows the incorrect effective date for the Drug, and what measures Cipla is taking to actively correct this incorrect reported date, among other things.
19. On April 26, 2021, Cipla sent a written response to the Additional Information Demand, which included additional documentary support of Cipla's responses to the Additional Information Demand, including documentary support that showed that Cipla had contacted and confirmed that the RED BOOK and Medi-Span databases now show the correct effective dates for the Drug.
20. The April 26, 2021 response letter from Cipla also included a copy of Cipla's February 1, 2021 new policy, implemented in response to the Investigation, which detailed new internal control

procedures that Cipla has put in place to ensure such inadvertent errors like the ones that occurred with the price reporting of the Drug do not occur in the future (the "Compendia Policy"). Cipla further stated that "[t]he purpose of the Compendia Policy is to 'emphasize a commitment' by Cipla 'toward the establishment of quality processes, procedures and guidelines related to the governance of all generic product Data Submissions…to the Data Compendia.' Compendia Policy at § 1.1".

21. After the Department reviewed Cipla's April 26, 2021 response letter and the additional documents submitted to the Department in support of the conclusions contained in the letter, on May 3, 2021, the Department conducted another telephone interview with leaders at Cipla. Among other topics Cipla set forth its commitment to implementing the internal control changes to ensure further errors of this type do not happen again.

22. The Department has concluded after a thorough investigation that the price of the Drug did not in fact increase but was instead launched in April 2020. Further, the Department has concluded that no consumer was harmed by the clerical error. The Department has received assurances from Cipla that no direct purchaser of the Drug from Cipla was impacted as the correct information on the launch price was always provided to vendors.

NOW, THEREFORE, it is hereby understood and agreed, by the Department and Cipla, as follows:

1. The Office of Pharmacy Benefits has jurisdiction over this matter pursuant to New York Insurance Law Section 111 and 11 NYCRR § 450.2.
2. Upon the Effective Date of this Agreement, the Department shall close its investigation into the perceived significant price increase of Budesonide 0.5 mg/2 mL inhalation, NDC

69097-0319-53, on the basis that the perceived significant increase of the Drug was due to an inadvertent clerical error, which has been subsequently corrected, and which caused no harm to consumers.

3. The Department will not refer its investigations into Budesonide 0.5 mg/2 mL inhalation to the Drug Accountability Board based on the findings stated in Paragraph 1 above.

4. Cipla has put in place changes to its internal controls governing the reporting of drug prices to drug compendia by putting in place a new policy entitled "Work Instructions For Data Compendia Submission Process" also known as the "Compendia Policy." This policy includes:

    a. A two-step verification process for all drug price submissions;

    b. Transfer of responsibility for drug price submissions to a Contract and Pricing Committee;

    c. Prior review and approval by the Chief Commercial Officer shall be required for all submissions; and

    d. Semiannual audits shall be conducted regarding pricing information.

5. Cipla's Chief Commercial Officer shall be designated the compliance office for internal controls related to drug price reporting and shall enforce the Compendia Policy.

6. Cipla shall submit to the Department one year after of the Effective Date of this Agreement an affidavit of compliance which includes details regarding how Cipla has continued to monitor and implement the internal control procedures put in place; affirming that Cipla will continue to exercise those internal controls in the future; and informing the Department of any changes made to Cipla's internal control procedures.

7. This Agreement, and the provisions contained herein, shall not be confidential and may be made publicly available by either Party, and the Parties are free to publicly disclose the findings of this Agreement in a written summary, press release, or otherwise.
8. The Department has agreed to the terms of this Agreement based on, among other things, representations made to the Department by Cipla, either directly or through counsel, and the Department's own factual investigation. To the extent that representations made by Cipla are later found to be materially incomplete or materially inaccurate, the Agreement is voidable by the Superintendent in their sole discretion.
9. Cipla represents and warrants, through the signatures below, that the terms and conditions of this Agreement are duly approved, and the execution of this Agreement is duly authorized.
10. This Agreement and any dispute thereunder shall be governed by the laws of the State of New York without regard to any conflicts of law principles.
11. This Agreement is binding on the Parties, as well as any successors and assigns. This Agreement does not bind any federal or other state agency or any law enforcement authority.
12. This Agreement may not be altered, modified, or changed unless in writing signed by the Parties hereto.
13. The Agreement shall be enforceable and remain in effect unless stayed or terminated in writing by the Superintendent or her designee.

14. This Agreement constitutes the entire agreement between the Department and Cipla and supersedes any prior communication, understanding, or agreement, whether written or oral, concerning the subject matter of this Agreement.
15. No inducement, promise, understanding, condition, or warranty not set forth in this Agreement has been relied upon by any Party to this Agreement.
16. In the event that one or more provisions contained in this Agreement shall for any reason be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement.
17. Upon the Parties' execution of this Agreement, the Department will discontinue the Investigation as to and against Cipla solely with respect to the practices set forth herein during the Relevant Period. No further action will be taken by the Department against Cipla for the conduct set forth in this Agreement provided Cipla complies with the terms of the Agreement.
18. Nothing in this Agreement shall be construed to prevent any consumer from pursuing any right or remedy at law.
19. This Agreement may be executed in counterparts, each of which shall be deemed to be an original copy hereof, but all of which, when taken together, shall be deemed to constitute one and the same agreement. This Agreement may be transmitted via facsimile or other similar electronic means and a signature of the undersigned transmitted via such means shall be deemed an original signature for all purposes and have the same force and effect as a manually signed original. This Agreement shall become effective when such

counterparts have been signed by each of the Parties hereto and So Ordered by the Superintendent or her designee (the "Effective Date").

WHEREFORE, the signatures evidencing assent to this Agreement have been affixed hereto on the dates set forth below.

THE DEPARTMENT OF FINANCIAL SERVICES

By: [redacted]
Allison Gold
Assistant Director, Office of Pharmacy Benefits

Dated: 1/22/2022

CIPLA USA, INC.

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By: [redacted]
A S Kumar
lobal General Counsel & EVP
22 January 2022 | 8:23:33 AM PST

IT IS SO ORDERED:

By: [redacted]
Eamon G. Rock
Deputy Superintendent for Pharmacy Benefits

Dated: 1/22/2022