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F. No. 6/50/2026-DGTR
Government of India
Department of Commerce
Ministry of Commerce and Industry
(Directorate General of Trade Remedies)
4th Floor, Jeevan Tara Building 5, Parliament Street, New Delhi - 110001

Dated: 24.09.2026

INITIATION NOTIFICATION

SETU CASE ID - AD/OI/053/2026

Subject: Initiation of anti-dumping investigation concerning imports of Montelukast Sodium from China PR

1. F. No. 6/50/2026-DGTR: Having regards to the Customs Tariff Act, 1975, as amended from time to time (hereinafter referred to as the 'Act') and the Customs Tariff (Identification, Assessment, and Collection of Anti-Dumping Duty on Dumped Articles and for Determination of Injury) Rules, 1995, as amended from time to time (hereinafter referred to as the 'Rules'), Morepen Laboratories Limited (hereinafter referred to as the 'applicant') has filed an application before the Designated Authority (hereinafter referred to as the 'Authority'), for initiation of an anti-dumping investigation on imports of Montelukast Sodium (hereinafter referred to as the 'product under consideration' or the 'subject goods' or the 'PUC'), originating in or exported from China PR (hereinafter referred to as the 'subject country').

2. The applicant has alleged that material injury is being caused to the domestic industry due to the dumped imports of the subject goods from China PR and has requested for the imposition of anti-dumping duties on the imports of the subject goods, originating in or exported from the subject country. It has been stated in the application that there are no concluded or ongoing trade remedy investigations relating to the product under consideration.

A. Product under consideration

3. The product under consideration in the present investigation is "Montelukast Sodium". Montelukast Sodium is the sodium salt of montelukast, having the molecular formula C35H35ClNNaO3S, a molecular weight of approximately 608.17 g/mol and CAS No. 151767-02-1. It is generally supplied as a white to off-white powder.

4. The PUC is primarily used as an active pharmaceutical ingredient (API) in the manufacture of pharmaceutical formulations for the treatment and management of

respiratory and allergic disorders, including asthma, rhinitis and formulations for the prevention of exercise-induced bronchoconstriction, and it may be used in tablets, chewable tablets, oral granules and fixed-dose combination products. It has been stated in the application that the PUC is freely importable, that the import, manufacture, sale and distribution of the PUC are regulated under the Drugs and Cosmetics Act, 1940 and the rules framed thereunder, and that the product is manufactured and traded in accordance with recognised pharmacopeial standards.

5. The scope of the PUC includes Montelukast Sodium in all forms, grades, purities, particle sizes and packaging, whether described as pharmaceutical grade, commercial grade, customer-specific grade or by any other nomenclature, provided that the product has the essential characteristics of Montelukast Sodium.

6. The unit of measurement considered in the present investigation for the product under consideration is Kilograms (KG).

7. The product under consideration has been imported under tariff items 2933 39 90, 2933 49 90, 2933 99 90 and 2942 00 90 of the First Schedule to the Customs Tariff Act, 1975. The customs classification is indicative only and is not binding on the scope of the present investigation.

8. The applicant has not proposed a Product Control Number ("PCN") methodology. All interested parties are advised to furnish their comments on the scope of the PUC and the proposed PCN methodology within 15 days from the date of transmission of the intimation letters, containing, inter alia, the non-confidential version of the application and the respective questionnaire(s), to the known interested parties and the diplomatic representative(s) of the subject country/countries.

B. Like article

9. The applicant has stated that there is no known difference between Montelukast Sodium produced by the applicant and the subject goods exported from China PR. The domestic product and the imported subject goods are comparable in terms of physical and chemical characteristics, functions and uses, pricing, distribution and marketing, and tariff classification; they are technically and commercially substitutable and are used interchangeably by consumers. Thus, for the purpose of initiation of the present investigation, the subject goods produced by the applicant are being treated as 'like article' to the product under consideration imported from the subject country.

C. Domestic industry & standing

10. The application has been filed by Morepen Laboratories Limited. The applicant has identified a number of other producers of the PUC in India and has stated that, apart

from a limited number of established producers, the remaining producers account individually for only a small proportion of the total Indian production. The applicant has further stated that it has neither imported the subject goods from the subject country nor is it related to any producer or exporter of the subject goods in the subject country or to any importer of the subject goods in India. There is no supporter of the application.

11. The applicant has stated that certain of the Indian producers manufacture the PUC primarily for captive consumption in the manufacture of downstream formulations intended for export and do not sell the PUC in the domestic market, and has accordingly furnished its share of the total Indian production both excluding and including the production of such producers. The Authority notes that the treatment of production intended for captive consumption bears upon the determination of the total Indian production of the like article for the purposes of Rule 2(b) and Rule 5(3) of the Rules. The Authority notes that on either basis the applicant accounts for a major proportion of the total Indian production of the like article and for more than the proportion prescribed under Rule 5(3) of the Rules, and that no other Indian producer has expressed either support for or opposition to the application. For the purpose of initiation it is therefore not necessary to determine whether the production of producers engaged primarily in captive consumption forms part of the total Indian production, and that question, together with the production of each of the known Indian producers, shall be examined in the course of the investigation.

12. Based on information available on record, the Authority is satisfied that the applicant constitutes domestic industry within the meaning of Rule 2(b). The application satisfies the requirements of standing in terms of Rule 5(3).

D. Subject country

13. The subject country in the present investigation is China PR.

E. Period of investigation

14. The applicant has proposed the period of investigation as 1st April 2025 to 31st March 2026, which is a period of 12 months. The Authority has considered the period of investigation as 1st April 2025 to 31st March 2026. The injury investigation period covers the financial years 2022-23, 2023-24, 2024-25 and the period of investigation.

F. Basis of alleged dumping

i. Normal value for China PR

15. The applicant has cited and relied upon Article 15(a) of China's Accession Protocol and has claimed that China PR should be treated as a non-market economy and that producers from China PR should be directed to demonstrate that market economy

conditions prevail in the industry with regard to the production and sales of the product under consideration. Unless the producers from China PR show that such market economy conditions prevail, their normal value should be determined in accordance with paragraphs 7 and 8 of Annexure-I to the Anti-Dumping Rules, 1995.

16. The applicant has submitted that information relating to the cost and price of the PUC in a market economy third country is not available in the public domain, and that it has no information with respect to the price of the like article from a market economy third country to other countries including India. The applicant has therefore constructed the normal value for China PR in terms of paragraph 7 of Annexure-I, based on its own weighted average cost of production adjusted to include a reasonable profit margin. The Authority notes that paragraph 7 of Annexure-I permits the determination of normal value on any other reasonable basis, including the price actually paid or payable in India for the like product duly adjusted to include a reasonable profit margin, where the anterior bases specified therein are not available. The methodology as claimed by the applicant has been considered for the purpose of initiation, and the availability of a market economy third country basis, as well as the elements of the constructed normal value, shall be examined in the course of the investigation.

ii. Export price

17. The export price of the product under consideration has been determined by considering the CIF price of Montelukast Sodium as reported in DG Systems transaction-wise import data. Appropriate adjustments have been considered on account of ocean freight, marine insurance, bank charges, port expenses, inland freight, and loading and unloading charges to arrive at the ex-factory export price.

iii. Dumping margin

18. The normal value and export price have been compared at the ex-factory level, which *prima facie* establishes that the dumping margin in respect of the product under consideration imported from China PR is positive and above the *de minimis* level. There is sufficient *prima facie* evidence that the product under consideration is being dumped into the domestic market of India by exporters from the subject country.

G. Injury and causal link

19. The applicant has alleged that the dumped imports of the subject goods from China PR are causing material injury to the domestic industry and has furnished *prima facie* evidence in support thereof. The information furnished by the applicant, read with the transaction-wise import data, *prima facie* shows that the subject imports, which were nil during the first two years of the injury period, commenced in 2024-25 and increased sharply during the period of investigation, both in absolute terms and in relation to the production and demand in India, attaining a significant share of the Indian market, while

imports from other sources remained negligible. The landed price of the subject imports declined steeply during the period of investigation and remained below the cost of sales of the domestic industry. The cost of sales of the domestic industry increased during that period while its selling price did not increase commensurately and was below its cost of sales. The production, capacity utilization, domestic sales and market share of the domestic industry declined, its inventories increased, and its profits, cash profits and return on capital employed turned negative during the period of investigation.

20. The Authority notes that the volume of the subject imports is not *prima facie* negligible. The Authority further notes that the landed price of the subject imports, though below the cost of sales of the domestic industry, remained marginally above its selling price, so that the subject imports are *prima facie* not undercutting the prices of the domestic industry, the adverse price effect of such imports being manifested in the constraint on the ability of the domestic industry to raise its prices to recover its increased cost of sales and also in its inability to produce and sell the PUC to the extent of its capacity to cater to demand. The Authority also notes that the demand for the subject goods in India declined during the period of investigation. Having regard to Annexure-II to the Rules, the Authority *prima facie* considers, for the purpose of initiation, that there is sufficient evidence of material injury to the domestic industry and of a causal link between the alleged dumping and such injury. The movement in demand, together with the other known factors, shall be examined in the course of the investigation so that injury, if any, caused by such factors is not attributed to the dumped imports.

H. Initiation of anti-dumping investigation

21. On the basis of the duly substantiated written application submitted by the applicant and having reached satisfaction based on the *prima facie* evidence submitted by the applicant concerning the dumping of the product under consideration originating in or exported from the subject country, the consequential material injury to the domestic industry as a result of the alleged dumping of the product under consideration and the causal link between such injury and the dumped imports, and in accordance with Section 9A of the Act read with Rule 5 of the AD Rules, the Authority, hereby, initiates an anti-dumping investigation to determine the existence, degree, and effect of the dumping with respect to the product under consideration originating in or exported from China PR and to recommend the appropriate amount of anti-dumping duty, which if levied, would be adequate to remove the injury to the domestic industry.

22. The applicant has requested the Authority to issue preliminary findings and to recommend imposition of provisional anti-dumping duty in terms of Rule 13 of the Rules, to recommend retrospective imposition of anti-dumping duty in terms of Rule 20(2)(b) of the Rules read with Section 9A of the Act. The Authority notes that these requests do not fall for determination at the stage of initiation. The same shall be

considered, if and to the extent warranted, at the appropriate stage of the investigation, and the interested parties may furnish their comments thereon within the time limit prescribed in this notification.

I. Procedure

23. The provisions stipulated in Rule 6 of the Anti-Dumping Rules shall be followed in this investigation.

J. Submission of information

24. All the interested parties are required to register themselves on **SETU Portal (http://setu.dgtr.gov.in)**. All communications and submissions from the interested parties shall be uploaded on the SETU portal under their registered name and corresponding case ID-AD/OI/053/2026. It should be ensured that the narrative part of the submission is in searchable PDF/MS-Word format and data files are in MS-Excel format.

25. The known producers/exporters in the subject country, the government of the subject country through its Embassy in India, and the importers and users in India known to be concerned with the subject goods are being informed separately to enable them to file all the relevant information within the time limits set out below.

26. Any other interested party may also make a submission relevant to the present investigation in the form and manner within the time limits set out below. Any party making any confidential submission before the Authority is required to make a non-confidential version of the same available to the other interested parties.

27. The interested parties are further advised to keep a regular watch on the official website of Directorate General of Trade Remedies at www.dgtr.gov.in and SETU portal (http://setu.dgtr.gov.in) for any updated information with respect to this investigation. Interested parties are directed to regularly visit the website of the DGTR (http://dgtr.gov.in/) to stay apprised with the further developments in the subject investigation and remain informed regarding notices that may be issued from time to time regarding questionnaire formats, PCN methodology, PCN discussion/meeting schedule, notice of oral hearing, corrigendum, amendment notifications and other such information.

K. Time limit

28. Any information relating to the present investigation must be uploaded by the interested parties on the SETU portal (http://setu.dgtr.gov.in) under their registered name and corresponding case ID - AD/OI/053/2026. Both version of each submission, the confidential version (CV) and the non-confidential version (NCV) must be uploaded in

the respective designated columns within 37 days from the date of transmission of the intimation letters, containing, inter alia, the non-confidential version of the application and the respective questionnaire(s), to the known interested parties and the diplomatic representative(s) of the subject country/countries, in accordance with Rule 6(4) of the Anti-Dumping Rules, 1995. If no information is received within the stipulated time limit or the information received is incomplete, the Authority may record its findings based on the facts available on record and in accordance with the AD Rules, 1995.

29. All the interested parties are hereby advised to intimate their interest (including the nature of interest) in the instant matter and file their questionnaire responses within the above time limit as stipulated in this notification through SETU portal only.

30. The 15-day period to file comments on the scope of the PUC/PCN Methodology shall run concurrently with the time limit mentioned in this initiation notification.

31. Extension due to Modification of PUC/PCN: An extension of time by 15 days shall be granted if the Authority, through a subsequent notice, modifies the PUC and PCN that was not previously proposed or is different from the initiation notification. The extension of 15 days shall be granted from date of such notification of modified PUC and PCN. Extension of time by 15 days stated in this paragraph is not applicable in instances where there is no change in the PUC and PCN methodology, after initiation of investigation. Requests for a further extension of time, beyond the 15 days extension (if granted), will ordinarily not be considered except in case of exceptional circumstances, in line with the Rules 6(4) of the AD Rules.

32. Any request for an extension must be submitted by the concerned parties through the SETU portal at least one day before the original deadline. Requests submitted after this time will not be considered.

L. Submission of information on confidential basis

33. Where any party to the present investigation makes confidential submissions or provides information on a confidential basis before the Authority, such party is required to simultaneously submit a non-confidential version of such information in terms of Rule 7(2) of the Rules and in accordance with the relevant trade notices issued by the Authority in this regard. Failure to adhere to the above may lead to rejection of the response/submissions.

34. The parties making any submission (including Appendices/Annexes attached thereto), before the Authority including questionnaire responses, are required to file confidential and non-confidential versions separately.

35. Such submissions must be clearly marked as 'confidential' or 'non-confidential' at the top of each page. Any submission that has been made to the Authority without such markings shall be treated as 'non-confidential' information by the Authority, and the Authority shall be at liberty to allow other interested parties to inspect such submissions.

36. The confidential version shall contain all information which is, by nature, confidential and/or other information, which the supplier of such information claims as confidential. For the information which is claimed to be confidential by nature, or the information on which confidentiality is claimed because of other reasons, the supplier of the information is required to provide a good cause statement along with the supplied information as to why such information cannot be disclosed.

37. The non-confidential version of the information filed by the interested parties should be a replica of the confidential version with the confidential information preferably indexed or blanked out (where indexation is not possible) and such information must be appropriately and adequately summarized depending upon the information on which confidentiality is claimed.

38. The non-confidential summary must be in sufficient detail to permit a reasonable understanding of the substance of the information furnished on a confidential basis. However, in exceptional circumstances, the party submitting the confidential information may indicate that such information is not susceptible to summary, and a statement of reasons containing a sufficient and adequate explanation in terms of Rule 7 of the Rules, 1995, and appropriate trade notices issued by the Authority, as to why such summarization is not possible, must be provided to the satisfaction of the Authority.

39. The interested parties can offer their comments on the issues of confidentiality within 7 days from the date of circulation of the non-confidential version of the documents.

40. Any submission made without a meaningful non-confidential version thereof or a sufficient and adequate cause statement in terms of Rule 7 of the Rules, and appropriate trade notices issued by the Authority, on the confidentiality claim shall not be taken on record by the Authority.

41. The Authority may accept or reject the request for confidentiality on examination of the nature of the information submitted. If the Authority is satisfied that the request for confidentiality is not warranted or if the supplier of the information is either unwilling to make the information public or to authorize its disclosure in generalized or summary form, it may disregard such information.

42. The Authority on being satisfied and accepting the need for confidentiality of the information provided, shall not disclose it to any party without specific authorisation of the party providing such information.

M. Inspection of public file

43. All non-confidential versions of submissions made by any interested party will be accessible to other interested parties through their respective login on the SETU Portal.

N. Non-cooperation

44. In case any interested party refuses access to and otherwise does not provide necessary information within a reasonable period or within the time stipulated by the Authority in this initiation notification, or significantly impedes the investigation, the Authority may declare such interested party as non-cooperative and record its findings based on the facts available and make such recommendations to the Central Government as it deems fit.

Digitally signed by
Amitabh Kumar
Date: 24-09-2026
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Amitabh Kumar
Designated Authority