BDMAI BULK DRUG MANUFACTURERS ASSOCIATION OF INDIA

2nd August 2025

The Secretary,
Ministry of Environment, Forest and Climate Change,
Indira Paryavaran Bhawan, Jor Bagh Road, Aliganj,
New Delhi-110003

Dear Sir

Sub: Request for Exemption of API Industry from Plastic Waste Management (PWM) Rules 2025.
Ref: Draft G.S.R 365 (E) Notified on 3rd June 2025

We refer to the draft G.S.R 365 (E) **Plastic Waste Management (PWM) Rules 2025**, notified on 3rd June 2025, and wish to submit the following concerns on behalf of our member companies engaged in the manufacture of Active Pharmaceutical Ingredients (APIs):

Our member companies are manufacturers of Active Pharmaceutical Ingredients which are the main ingredient which brings therapeutic value to the medicines. Being critical to the Human health, the Industry is governed by Drugs and cosmetic rules of not only our country but also of all the other countries wherever these medicines are being exported.

Indian Pharmaceutical Industry is Global leader & supplies medicines to almost 195 countries of the world. Our member Companies primarily use LDPE (Clear and Black) drums for packing APIs, which are supplied to the manufacturers of finished formulations. Since these formulations are intended for human consumption, every aspect of manufacturing, packaging, storage, and transportation is subject to stringent regulations by both Indian and international regulatory authorities.

In adherence to these standards, the usage of recycled plastic materials is strictly avoided due to the following reasons:

- **Risk of Contamination**: Recycled plastics may carry residual chemicals or substances from previous use, which could compromise the purity and safety of APIs.
- **Inconsistent Material Quality**: Recycled materials often lack uniformity in strength, purity, and performance, potentially impacting the integrity of pharmaceutical packaging.
- **Chemical Interactions**: There is a possibility that recycled plastics may react chemically with the APIs, jeopardizing product stability or generating unintended impurities.

C-25, Industrial Estate, Sanathnagar Hyderabad - 500 018 Ph : 040-23706718/3910/4804
info@bdmai.org www.bdmai.org

- **Regulatory Restrictions**: Global regulatory agencies generally prohibit the use of recycled plastics in direct-contact pharmaceutical packaging unless validated through extensive safety studies.

- **GMP and Quality Compliance**: As per current Good Manufacturing Practices (cGMP), only virgin (unused) pharma-grade plastics are permitted for drums and liners used in pharmaceutical packaging.

- **Color Consistency Requirement**: Variations in color from using recycled plastics may result in non-compliance with drug regulatory standards. API manufacturers are required to declare and maintain uniform color shades of packaging to ensure traceability and prevent any possibility of tampering or substitution.

In view of the above, we submit that the API industry must be allowed to continue to use virgin pharma-grade plastic packaging for both primary and secondary packaging to safeguard product integrity and patient safety.

We hereby respectfully request that the API manufacturers may be **exempted** from the provisions of the draft PWM Rules 2025. In case any additional technical information or documentation is required to support our request, we would be pleased to provide the same.

Thank you for your kind consideration.

Yours sincerely,

BULK DRUG MANUFACTURERS ASSOCIATION Hyderabad

M Roja Rani
Executive Director.