

## Module 5.3: Adverse Experience Reports

### TABLE OF CONTENTS

1.	STUDY INTRODUCTION .....	2
2.	CONSUMER COMPLAINTS ANALYSIS .....	2
3.	ADVERSE EVENTS .....	3
4.	DISCUSSION .....	5

## 1. STUDY INTRODUCTION

We provide Consumer Complaint and Adverse Event data for the *proposed MRTPs* and *authorized MRTPs* for calendar year 2023, including comparative information.<sup>1</sup> This material is consistent with the data and information provided in the corresponding PMTAs, which is in the (b) (4).<sup>2</sup>

## 2. CONSUMER COMPLAINTS ANALYSIS

Between January 1, 2023, and December 31, 2023, we received (b) (4) consumer complaints for the *proposed MRTPs*, with (b) (4) cases reported for the 6 mg products, (b) (4) cases reported for the 3 mg products, and (b) (4) cases reported where no product strength was specified. For the remaining (b) (4) cases, no product variant was specified.

The most frequently reported complaints overall (> 5%) were as follows:

- Pouch Rips/Tears/Opens (b) (4)
- Short Count (b) (4)

For the 6 mg *proposed MRTPs*, the most frequently reported complaints (> 5%) were as follows:

- Pouch Rips/Tears/Opens (b) (4)
- Short Count (b) (4)

For the 3 mg *proposed MRTPs*, the most frequently reported complaints (> 5%) were as follows:

- Pouch Rips/Tears/Opens (b) (4)
- Short Count (b) (4)
- Flavor/Aroma (b) (4)

Between January 1, 2023, and December 31, 2023, we received (b) (4) consumer complaints for the *authorized MRTPs*; (b) (4) cases were reported for General Mint Portion White Large, (b) (4) cases reported for General Portion Original Large, (b) (4) cases reported for General Portion White Large, (b) (4) cases reported for General Wintergreen Portion White Large, and for the remaining (b) (4) cases reported, no product variant was specified.

The most frequently reported complaints (> 5%) were as follows:

- Flavor/Aroma (b) (4)
- Pouch Rips/Tears/Opens (b) (4)
- Underfilled (b) (4)

For the individual *authorized MRTPs*, the most frequently reported complaints (> 5%) were as follows:

- General Mint Portion White Large
  - Pouch Rips/Tears/Opens (b) (4)
  - Flavor/Aroma (b) (4)
  - Packaging Issue (b) (4)
  - Underfilled (b) (4)
  - Outdated (b) (4)

<sup>1</sup> See Attachment 5-3-1 for complete adverse experience data.

<sup>2</sup> AE data reported in the original PMTAs is in (b) (4)

and (b) (4)

- Short Count (b) (4)
- General Portion Original Large
  - Flavor/Aroma (b) (4)
  - Pouch Rips/Tears/Opens (b) (4)
  - Short Count (b) (4)
  - Outdated (b) (4)
- General Portion White Large
  - Flavor/Aroma (b) (4)
  - Underfilled (b) (4)
  - Pouch Rips/Tears/Opens (b) (4)
- General Wintergreen Portion White Large
  - Pouch Rips/Tears/Opens (b) (4)
  - Flavor/Aroma (b) (4)
  - Off texture (b) (4)
  - Underfilled (b) (4)
  - Short Count (b) (4)

Given the differences in reporting and sales volumes, the consumer complaints data for both the *proposed MRTPA's* and *authorized MRTPA's* was normalized for sales volumes. The sum of product defects per million opportunities<sup>3</sup> (DPMO) from Jan 1, 2023, until Dec 31, 2023 for the *authorized MRTPA's* is (b) (4) cans and (b) (4) cans for the *proposed MRTPA's*. Each < 3.4 represents Six Sigma quality performance.

### 3. ADVERSE EVENTS

Between January 1, 2023, and December 31, 2023, there were (b) (4) adverse events reported<sup>4</sup> in the United States for the *proposed MRTPA's*<sup>5</sup>; (b) (4) events were reported for the 6 mg products, (b) (4) events were reported for 3 mg products, and for the remaining (b) (4) events reported, no product variant was specified. Of the (b) (4) total reports, (b) (4) events were assessed as non-serious, and (b) (4) was assessed as serious.<sup>6</sup>

Overall, for the *proposed MRTPA's*, the most frequently reported events (> 5%) were as follows:

(b) (4)

<sup>3</sup> Total No. of complaints / (sale X case reasons)] X 1,000,000 = < 3.4 defects per million opportunities Six Sigma quality performance

<sup>4</sup> These events are based upon user self-reported information and have not been verified as having occurred.

<sup>5</sup> Exclusions: Three non-serious cases reported products verified as not distributed in the U.S. One case reported the total absence of data. Duplicate cases were removed.

<sup>6</sup> The seriousness was assessed using the criteria established in ICH-E2A (ICH. ICH E2A Clinical safety data management: definitions and standards for expedited reporting - Guideline. (1994).

For the 6 mg *proposed MRTPA's*, the most frequently reported events (> 5%) were as follows:

(b) (4)

For the 3 mg *proposed MRTPA's*, the most frequently reported events (> 5%) were as follows:

(b) (4)

The reported event assessed as serious concerns an (b) (4) consumer of an unspecified variant of the *proposed MRTPA's* who experienced a (b) (4). The event was assessed as serious based on Important Medical Event criteria.<sup>6</sup> The reported verbatim was (b) (4). We followed up with the consumer to obtain the product for further evaluation and more information about the event; however, the consumer no longer had the product. Information was provided to the consumer to inform discussion with their doctor and no further contact from the consumer was documented after this. Without further information (b) (4) it is impossible to assess the causal relationship between the event and use of the *proposed MRTPA's*.<sup>7</sup>

Between January 1, 2023, and December 31, 2023, there was one adverse event reported in the United States for the *authorized MRTPA's*. The event was assessed as non-serious, for *gingival discomfort*. Specifically, the event was reported for General Mint Portion White Large.

As with assessment of the consumer complaints, we normalized the adverse events data for the *proposed MRTPA's* and the *authorized MRTPA's* by sales volumes. The sum of product DPMO<sup>3</sup> between January 1, 2023, and December 31, 2023, for the *authorized MRTPA's* is (b) (4) and (b) (4) for the *proposed MRTPA's*. Each < 3.4 represents Six Sigma quality performance.

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<sup>7</sup> Case notes for this incident have been provided in [Attachment 5-3-2 \(Case 00521418 Case Notes\)](#).

#### 4. DISCUSSION

The types of consumer complaints and reported adverse events are similar for the *proposed MRTPs* and *authorized MRTPs*. Overall, both product lines experience a very low level of consumer complaints and reported adverse events, relative to the respective U.S. market volumes. Additionally, of the 1,303 events reported in the Tobacco Product Reports<sup>8</sup> (TPPRs) between 2017 and 2023, none reported nicotine pouches and only four cases reported snus products (pouches or loose). The majority of reported events are not unexpected and related to nicotine use. The types of events reported are similar in nature to those observed with oral nicotine replacement therapy products as well. These data demonstrate the *proposed MRTPs* are similar to the *authorized MRTPs* in both the types and relative quantities of adverse experiences reported. Thus, no new health risks or adverse events are associated with use of the *proposed MRTPs* compared to those associated with use of the *authorized MRTPs*.

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<sup>8</sup> Tobacco Product Problem Reports | FDA

<https://www.fda.gov/tobacco-products/tobacco-science-research/tobacco-product-problem-reports#>