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Quarterly Medical Device Warning Letters Update: July – September 2024

October 23, 2024

Medical Devices and Diagnostics

This client alert summarizes trends and otherwise notable allegations in publicly available FDA warning letters relating to medical devices. This alert summarizes trends in the warning letters issued in the third quarter of 2024 (July through September).[1]

As of October 23, 2024, eleven warning letters issued in the third quarter of 2024 alleging violations of the Food, Drug, and Cosmetic Act (FDCA) related to medical devices were posted by FDA.[2] Key trends and otherwise notable allegations in the warning letters this quarter include:

1. **Most Commonly Cited Violations**: Five of the eleven letters allege violations of the quality system regulations (QSR). The alleged violations relate to design controls under 21 CFR 820.30 and corrective and preventive action (CAPA) under 21 CFR 820.100, each of which were cited in four of those five letters. This is the third consecutive quarter in which QSR violations were the most commonly cited violations with design controls as a particular focus, and the second quarter this year that CAPAs have been a particular focus.

2. **Third-Party Testing Laboratories**: This quarter, FDA issued two warning letters alleging violations of Good Laboratory Practice (GLP) requirements to nonclinical testing laboratories in China that provide third-party testing and validation data services to device manufacturers for use in their premarket device submissions to FDA. FDA alleges that "serious" and "systemic" violations at the testing facilities raised concerns about the quality and integrity of the data, and states that it could initiate disqualification proceedings. These warning letters follow FDA's earlier announcement in February of

[1] This alert summarizes some of the allegations contained in FDA's letters. It does not contain any analyses, opinions, characterizations, or conclusions by Covington & Burling LLP. The information presented herein does not necessarily reflect the views of Covington & Burling LLP or any of its clients.

[2] These warning letters include only those that were publicly posted by FDA as of the date listed, including: CMS #686915 (July 12, 2024), CMS #685606 (July 15, 2024), CMS #687035 (July 18, 2024), CMS #687033 (July 18, 2024), CMS #676842 (Aug. 7, 2024), CMS #676849 (Aug. 7, 2024), CMS #677297 (Aug. 7, 2024), CMS #677092 (Aug. 8, 2024), CMS #683606 (Aug. 13, 2024), CMS #687970 (Sept. 10, 2024), and CMS #687111 (Sept. 10, 2024). Late posted letters will be addressed in a future client alert.

this year alerting device manufacturers that an increasing number of third-party test labs are generating testing data that are fabricated, duplicated from other device submissions, or otherwise unreliable. In a press announcement released when the warning letters were published, FDA states that it "continues to conduct a rigorous review of data generated from these facilities, submitted in premarket submissions, and does not intend to authorize submissions where the data are necessary for the FDA to make a marketing authorization decision, as such data are found to be unreliable." FDA also states that it is "evaluating any impact these findings have had on past submissions and will take action to address any public health risks as necessary."

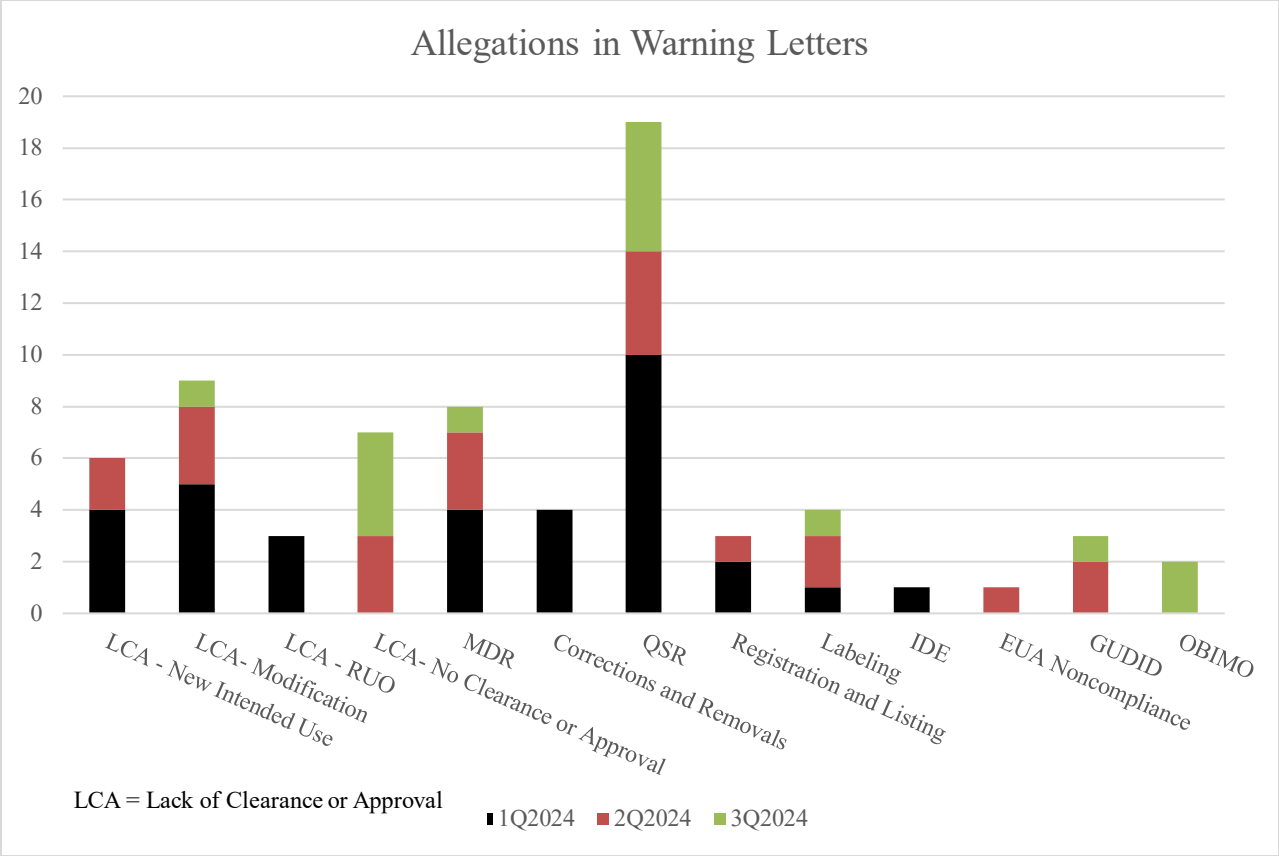
3. **CPAP Accessories**: FDA issued four warning letters alleging that products promoted to clean and sanitize CPAP therapy devices and accessories are unapproved and uncleared devices. FDA rejected arguments from the companies that their products were not devices or that their products were Class I 510(k)-exempt general purpose disinfectants.

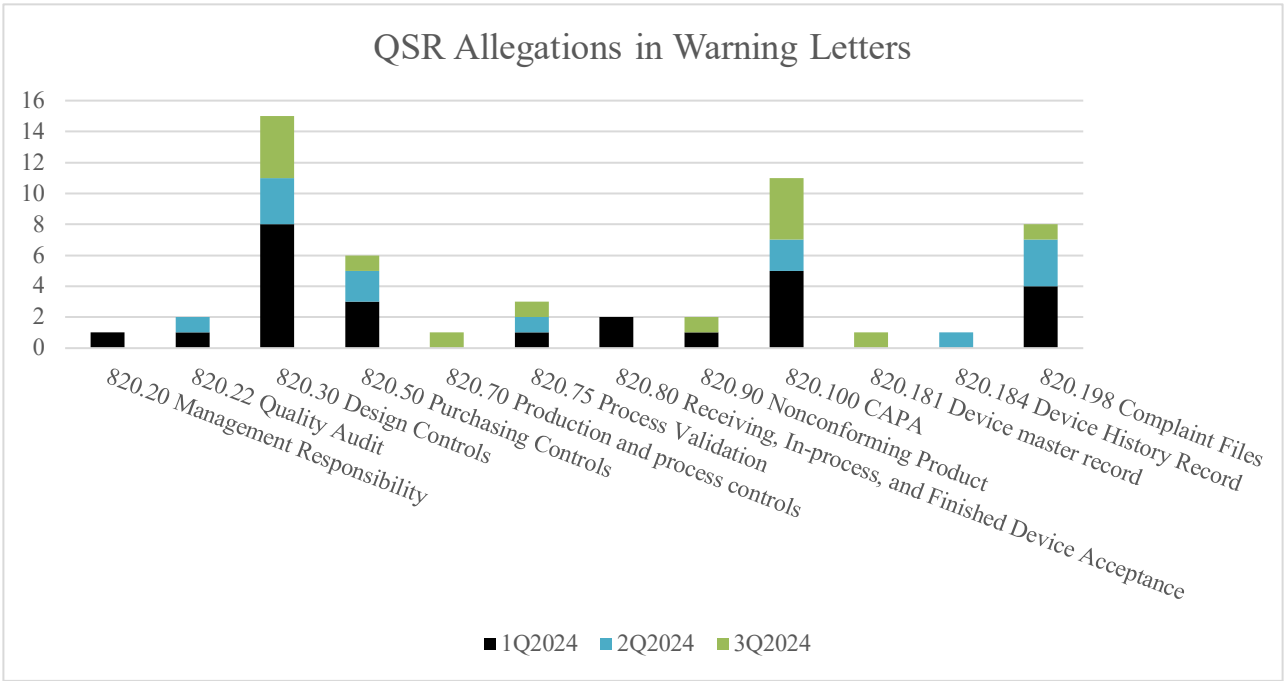
4. **More Warning Letters for Syringes from China**: FDA issued two warning letters related to the Agency's ongoing concerns with syringes manufactured in China. As noted earlier, last year FDA issued a safety communication to consumers, health care providers, and health care facilities raising quality issues associated with several Chinese manufacturers of syringes. FDA had issued four warning letters associated with syringes manufactured in China in the first half of this year, and the Agency issued two more such warning letters this quarter, on July 18, 2024. The additional warning letters allege design control and CAPA violations.

5. **Request for an Outside Consultant Audit**: In a warning letter to Criticare Technologies, Inc. alleging QSR violations, FDA requests that Criticare have an outside expert consultant perform a quality system audit of its establishment's manufacturing and quality assurance systems. FDA further requests that the company submit (1) a certification from such consultant, (2) a copy of the consultant's report, and (3) a certification from the establishment's Chief Executive Officer (CEO) that they have reviewed the report and initiated or completed all corrections called for in the report. FDA states that subsequent certification of updated audits and corrections (if required) should be submitted annually for the next two years, as well.

6. **Unique Device Identifier (UDI) Violations**: For the second quarter in a row, FDA issued a letter alleging labeling violations because a device lacked a device identifier and violations of the separate requirement for "labelers" to submit information to FDA's Global Unique Device Identifier Database (GUDID). This letter included additional allegations, related to lack of clearance or approval for modifications and QSR violations.

The allegations in the warning letters sent this quarter can be grouped into the following categories:


Allegations in Warning Letters
20
18
16
14
12
10
8
6
4
2
0
LCA - New Intended Use
LCA- Modification
LCA - RUO
LCA- No Clearance or Approval
MDR
Corrections and Removals
QSR
Registration and Listing
Labeling
IDE
EUA Noncompliance
GUDID
OBIMO
LCA = Lack of Clearance or Approval
1Q2024
2Q2024
3Q2024


QSR Allegations in Warning Letters
16
14
12
10
8
6
4
2
0
820.20 Management Responsibility
820.22 Quality Audit
820.30 Design Controls
820.50 Purchasing Controls
820.70 Production and process controls
820.75 Process Validation
820.80 Receiving, In-process, and Finished Device Acceptance
820.90 Nonconforming Product
820.100 CAPA
820.181 Device master record
820.184 Device History Record
820.198 Complaint Files
1Q2024
2Q2024
3Q2024

If you have any questions concerning the material discussed in this client alert, please contact the members of our Medical Devices and Diagnostics group.

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