IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY | an informa business
Unlimited Validation Knowledge Awaits...
Published on *IVT Network* (http://www.ivtnetwork.com)

Ventilators Dumped in Miami - BLOG

By **Vladimir Gostuski May 26, 2021 7:00 am EDT**

Recently, Miami's Local 10 news did a report on a large quantity of brand-new, still packaged, mechanical ventilators being dumped in a landfill1. According to Local 10, the ACM812A ventilators manufactured by Beijing Aerospace Changfeng Ltd were brought into the U.S. during the Spring of 2020 by an unidentified entity. The ventilators had to be either destroyed or taken outside of the country because they were not on the FDA's list of ventilators under Emergency Use Authorization (EUA) for the COVID-19 pandemic. On a follow-up of the story2, Local 10 posted an FDA Import Refusal Report dated Oct. 29th, 2020 stating "Misbranding" as the reason the FDA did not allow the entry of the ventilators. The FDA's online resources can be navigated to fact-check Local 10's coverage.

The FDA defines an Import Refusal as "FDA's final decision that a detained shipment is in violation of FDA laws and regulations. A refused shipment must either be destroyed or exported under the supervision of Customs and Border Protection (CBP) and FDA within 90 days of the date of the Notice of FDA Action (Refusal Notice)"3. The Import Refusal Report (IRR) posted by Local 10 can be found by navigating to the FDA's IRR database search4, selecting Product, October in the month field, 2020 for the year, and finally 73-Anestheseology for the product category. After a short scroll, four entries for "BEIJING AEROSPACE CHANGFENG CO.," can be found. The reports list Product Code as "73CBK", FDA Product Description as "VENTILATOR, CONTINUOUS (RESPIRATOR)", Refusal Date "29-Oct-2020", and FDA District as "DNEI". The charges for the IRR are Violation code ''NO 510(K)", Section 801(a)(3); 502(o) Misbranding, Charge Statement "The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a post 1976 device for which a Section 510(k) application has not been determined substantially equivalent or a 510(k) has not been filed."

From this information it is hard to determine if the ventilators in the IRR are the same as the ones being dumped in Miami. The IRR does not state the device model, and the Beijing Aerospace Changfeng Ltd website shows three ventilators with differing specifications and accessories under the ACM812A model. The refusal date is Oct. 29th, 2020, and the ventilators were supposedly dumped in April 2021, far from the 90-day deadline. Also, the listed FDA district corresponds to the Division of Northeast Imports (DNEI), and Florida corresponds to the Division of Southeastern Imports (DSEI).

The FDA Detention & Hearing webpage5 states that once a product is detained, a "Notice of Detention and Hearing" is emitted to the importer, owner, and/or consignee, with a respond-by date for an appeal to be made. This period is usually ten to twenty days and allows for extensions when a reasonable request is made. After an appeal is made, if the FDA considers the product to still be in violation of a requirement an Import Refusal is emitted, and the 90-day period to either destroy or export the product starts running with no further delays allowed. This leaves the deadline for disposal of the ventilators around late January 2021. The FDA, however, does not require a product to remain in a physical location before its admissibility is determined. So, the products may have entered through a port corresponding to the DNEI and were then transported to Miami. There are also no other IRRs for Beijing Aerospace Changfeng Ltd from at least a year before April 2021, so the IRR presented by Local 10 may correspond to the trashed ventilators, although the timeframes for the disposal dates are

inconsistent.

The violation was that the ventilators either did not have a 510(k)-application determined to be substantially equivalent, or a 510(k) was not filed. Searching the Product Classification database for code CBK6, we can confirm that it corresponds to a Class 2 medical device, and the submission process type is a 510(k). This means that the ACM812A ventilators could have been determined substantially equivalent prior to the COVID-19 pandemic and issuance of the EUA. If this were the case, they would not be included in the list of approved ventilators under EUA Appendix B7, which does not include all ventilators with previous 510(k) clearance. This is true except for the case in which a previously cleared device undergoes a modification that requires a manufacturer to submit a new premarket approval. A search for the keywords “ACM812”, “ACM812A” for Device Name and “BEIJING AEROSPACE CHANGFENG CO.,” for Applicant Name in the 510(k) Premarket Approval database8 returns no results.

Without previous 510(k) clearance, the only option for the ventilators to enter the U.S. market was through a EUA, as per the requirements in the Letter of Authorization9. If the safety, performance, and labeling criteria are met, the ventilators are included in Appendix B of the EUA. Otherwise, the device is determined non-eligible, and the product cannot enter the U.S. These two outcomes are likely what happened to the ACM812A ventilators.

The first possible scenario is that the request for EUA was not presented with sufficient time for the FDA to review and approve it before the ventilators arrived in the U.S. This means there is a possibility that the ventilators met the EUA requirements but were simply not approved in time due to bad timing or delayed paperwork. The second senario is that the EUA request was made, but the ventilators did not meet the requirements, so they were not allowed to enter the U.S.

The Beijing Aerospace Changfeng Ltd website claims one of the ACM812A ventilators has CE marking, and the Local 10 video shows boxes with CE markings on them. If this were so, the first scenario is a likely possibility, since it is easier for a product already approved by the EU to gain approval by the FDA. The coverage by Local 10 leads in the right direction. The fact that the ventilators were not on the EUA list is mentioned on the first report as the cause for them being turned down, but this is only partially true. They were turned down because they either did not have a previous 510(k) clearance, or they did not have an EUA. This is covered on the second report, where “Misbranding” is stated as the reason the ventilators were not accepted. As is explained in the Labeling requirements – Misbranding page10, “The establishment is not registered with FDA as required by Section 510 of the FFDCA and has not listed the device as required by Section 510(j) of the FFDCA or obtained applicable premarket notification clearance as required by Section 510(k) of the FFDCA” is considered a case of misbranding. This checks out with the Violation Code on the IRR. The time between the IRR and the disposal of the ventilators is not clear, but there might be some mechanism for its extension that was missed in this analysis.

SUMMARY

Whatever truly happened, the person responsible for the ventilators decided that the destruction of the devices was the best option, for whatever reason, be it economical and/or practical. It is interesting to see how the COVID-19 pandemic made subjects such as the FDA’s work more present than ever to the public. For Biomedical Engineers, it is an opportunity to learn more about the world’s most important regulatory agency that is also intrinsic to our field. In this case, simply delaying a shipment or presenting paperwork earlier might have saved a very valuable resource for the COVID-19 pandemic and an important economic loss. Regardless of the case, being knowledgeable of regulatory affairs can only improve our work and help us avoid costly mistakes.

REFERENCES

1. Milberg, G., 2021. Why are new ventilators being trashed in a Miami-Dade landfill? WPLG. Available at: https://www.local10.com/news/local/2021/04/19/why-are-new-ventilators-be...
2. Milberg, G., 2021. Local 10 Investigates: More details on brand-new ventilators dumped in Miami-Dade landfill. WPLG. Available at: https://www.local10.com/news/local/2021/04/26/local-10-investigates-disc...
3. Affairs, O. of R., 2018. Refusal of Imported Products. U.S. Food and Drug Administration. Available at: https://www.fda.gov/industry/actions-enforcement/import-refusals
4. Anon, 2015. Import Refusal Report. accessdata.fda.gov. Available at: https://www.accessdata.fda.gov/scripts/ImportRefusals/index.cfm
5. Affairs, O. of R., 2020. Detention & Hearing Period for Imported Products. U.S. Food and Drug Administration. Available at: https://www.fda.gov/industry/actions-enforcement/detention-hearing

6. Anon, 2021. Product Classification. accessdata.fda.gov. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification....
7. Center for Devices and Radiological Health, 2021. Ventilators and Ventilator Accessories EUAs. U.S. Food and Drug Administration. Available at: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-em...
8. Anon, 2021. 510(k) Premarket Notification. accessdata.fda.gov. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm
9. Hinton, D.M., 2020. Emergency Use Authorization (EUA) Ventilators. US Food and Drug Administration. Available at: https://www.fda.gov/media/136423/download.
10. Center for Devices and Radiological Health, 2017. Labeling requirements regarding misbranding. U.S. Food and Drug Administration. Available at: https://www.fda.gov/medical-devices/general-device-labeling-requirements...
