FDA Compliance for PPEs

Newsletter III

May,2020

- The US, along with multiple other countries, also found some faults with PPEs and testing kits from China in the recent weeks
- As a result, some large companies and even states like Georgia cancelled contracts with Chinese manufacturers of test kits with low accuracy rates
- To meet the new and rapid global demand, more than 38,000 new companies have registered in 2020 to make or trade face masks in China, compared to 8,594 during the previous year. This has led to increased quality concerns and fraudulent claims of standards as reported by a few companies
- The DOJ announced in the month of March that it will crack down on hoarders that mark up the price. The U.S. Department of Justice (DOJ) and U.S. Department of Health and Human Services (HHS) today announced the distribution of hoarded personal protective equipment (PPE), including approximately 192,000 N95 respirator masks, to those on the frontline of the response in New York and New Jersey
- A recent testing of KN95 respirators sample from China (KN95 being Chinese variant of N95) revealed some products had filtration below the required 95% efficiency rate proving substandard, non-performing and ultimately dangerous. One case found with lowest range from 45%-30% in efficiency and this product was fraudulently marked as FDA approved
- We at Dragon Sourcing present the FDA compliance and approval process in this newsletter in a simple and concise format. Suppliers and other who are interested in learning about the exact process should go through FDA website and follow process described by the FDA

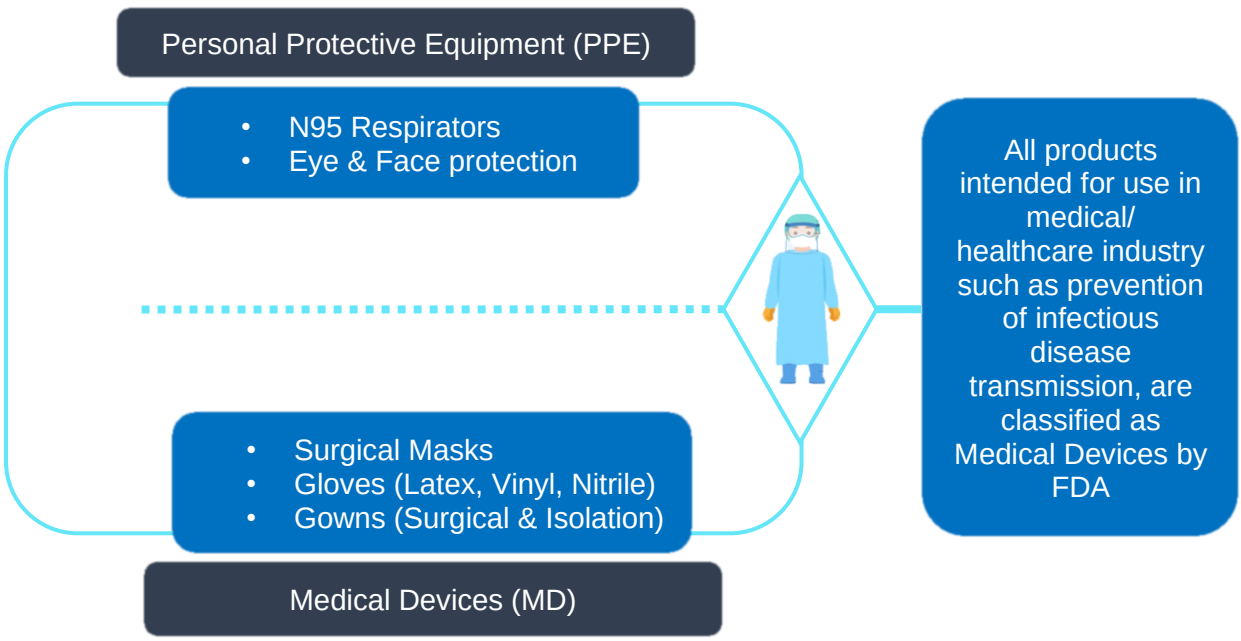
Category in Scope and FDA Class & Regulation

Products	Gloves		Gowns		Masks	Respirators	
Type	Surgical Gloves	Examination Gloves	Surgical Gowns & Surgical Isolation Gowns	Non Surgical Gowns	Surgical Mask	N95	N99
FDA Submission & Class	510(k) Class I		510(k) Class II	510(k) Exempt Class I	510(k) Class II	510(k) Class II	
Regulation	21 CFR 878.4460	21 CFR 880.6250	21 CFR 878.4040		21 CFR 878.4040	21 CFR 878.4040	21 CFR 878.4460
FDA Passed Products are called	FDA Cleared		FDA Cleared		FDA Cleared	FDA Cleared	
NIOSH	NA		NA		NA	Mandatory	

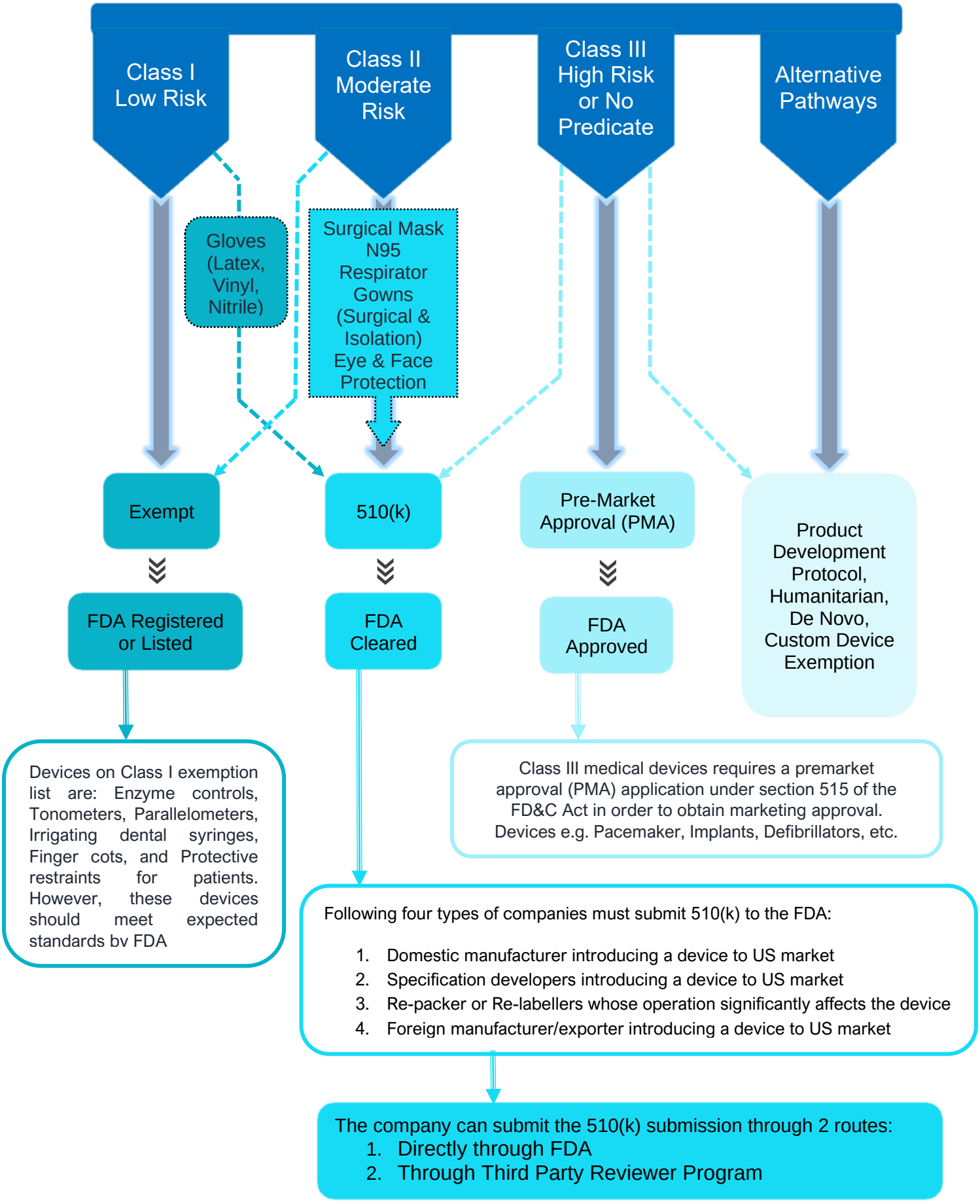
There are significant differences between surgical masks and N95 respirators per FDA classification. This is because N95 masks fall under PPE and will have to go through NIOSH standards approval while surgical masks fall under medical devices categories and will be under purview of FDA only

#	Surgical Mask	N95 Respirator
Testing & Approval	Cleared by FDA	Evaluated, Tested & Approved by NIOSH
Intended Use & Purpose	Fluid Resistance against large droplets, splashes or sprays of bodily or hazardous fluids. Protects the patient from wearer's respiratory emissions	Reduces wearer's exposure to particles including small particle aerosols (only non-oily) & large droplets
Face Seal Fit	Loose Fitting	Tight Fitting
Fit Testing Requirement	No	Yes
User seal check requirement	No	Yes, each time it is donned
Filtration	Does NOT provide protection from inhaling small airborne particles & is not considered respiratory protection	Filters out at least 95% of large & small airborne particles
Leakage	Leakage occur around the edge when user inhales	When properly fitted and donned, minimum leakage occur around the edge when user inhales
Use Limitations	Disposable. Discard after each use	Ideally should be discarded after each use or any damage or dirt

Category Classification by FDA



FDA Medical Device Classification



Manufacturer/Supplier must meet the requirement of 510(k) submission. Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be Substantially Equivalent (SE) and states that the device can be marketed in the US. This order “clears” the device from commercial distribution.

The 510(k) Submission Process Direct through FDA

A 510(k) submission must be submitted in an electronic format (eCopy). should be sent to CDRH’s or CBER’s Document Control Center (DCC), which is available on eCopy Program for Medical Device Submissions

When the DCC receives the 510(k) submission, it assigns the submission a unique control number "510(k) number," or "K number", begins with K followed by 6 digits

If the proper user fee has not been paid and/or a valid eCopy has not been provided, then the DCC will email a Hold Letter to the 510(k) submitter, usually within 7 days of receipt of the 510(k). Submitter needs to resolve it within 180 days. If not resolved, it will be considered as withdrawn and has to submit new 510(k) FDA marketing clearance

After the Acknowledgement Letter is sent, the DCC routes the 510(k) to the appropriate ODE or OIR Division

Within 15 days of the receipt of the submission, the submitter will receive an electronic notification of the Acceptance Review result, which will: Identify name & contact information of FDA Lead Reviewer and Indicate the status

If the Lead Reviewer sends an AI (Additional Information) Request, the submission is placed on hold. The submitter must submit the response, with a valid eCopy, to the DCC within 180 calendar days of the date of the AI Request; including include the submitter’s name; 510(k) number; identify the submission as Additional Information (AI) to the 510(k); date of FDA's request for AI and provide the requested information in an organized manner

When a decision is made, FDA will issue the decision letter to the submitter by email to the email address provided in the 510(k) cover letter. A 510(k) that receives an SE decision is considered "cleared." And submitter will be added in the 510(k) database, which is updated weekly.

FDA Process Timeline

By Day 1
- FDA receives 510(k) submission

By Day 7
- FDA Sends Acknowledgement Letter OR
- FDA Sends Hold Letter if unresolved issue with User Fee and/or eCopy

By Day 15
- FDA conducts Acceptance Review
- FDA informs submitter if 510(k) is accepted for Substantive Review or placed on RTA Hold

By Day 60
- FDA conduct Substantive Review
- FDA communicates via Substantive Interaction to inform the submitter that the FDA will either proceed with Interactive Review or that the 510(k) will be placed on hold and Additional Information is required

By Day 90
- FDA sends final MDUFA (Medical Device User Fee Amendments) Decision on 510(k)

By Day 100
- If MDUFA Decision is not reached by Day 100, FDA provides missed MDUFA Decision communication that identifies outstanding review issues

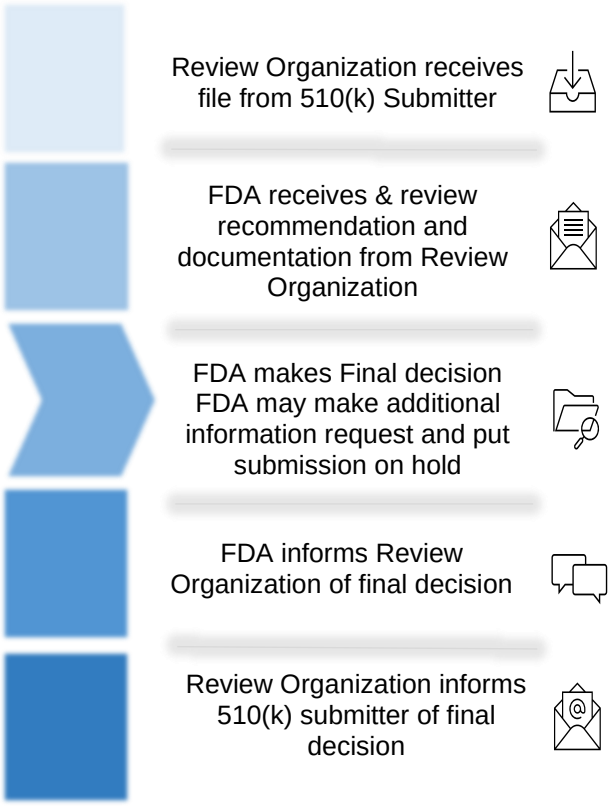
The process for 510(k) Submission through 3P510k (Third Party Program)

Under the Third Party Review Program, a 510(k) submission for an eligible device may first be submitted to an accredited 3P510k Review Organization rather than directly to the FDA. Use of this program is voluntary.

The sole payment under the program is between the 510(k) submitter and the 3P510k Review Organization; there is no separate payment (i.e., user fee) to the FDA.

3P510k Review Organizations use the same criteria used by the FDA to review 510(k) submissions.

- ✓ *Determine if your device is eligible on* FDA's Device Classification Database or can Contact the FDA at 3P510k@fda.hhs.gov
- ✓ Find and contact a 3P510k Review Organization that can review your 510(k) using the List of Devices for Third Party Review page and the list of 3P510k Review Organizations (also referred to as Accredited Persons)
- ✓ Obtain price quotes from one or more 3P510k Review Organizations and make a contract for a review
- ✓ Submit the 510(k) to the 3P510k Review Organization. The submission should include:
    - A letter authorizing the 3P510k Review Organization to discuss the 510(k) with the FDA and to forward it to the FDA on the 510(k) submitter's behalf. The letter should include:
    1. Name of the 3P510k Review Organization;
    2. Name and contact information of the person assigned to the review; and
    3. Device trade name.
    - The complete 510(k) submission, including the supporting data, summaries and analysis in the format requested by the 3P510k Review Organization.

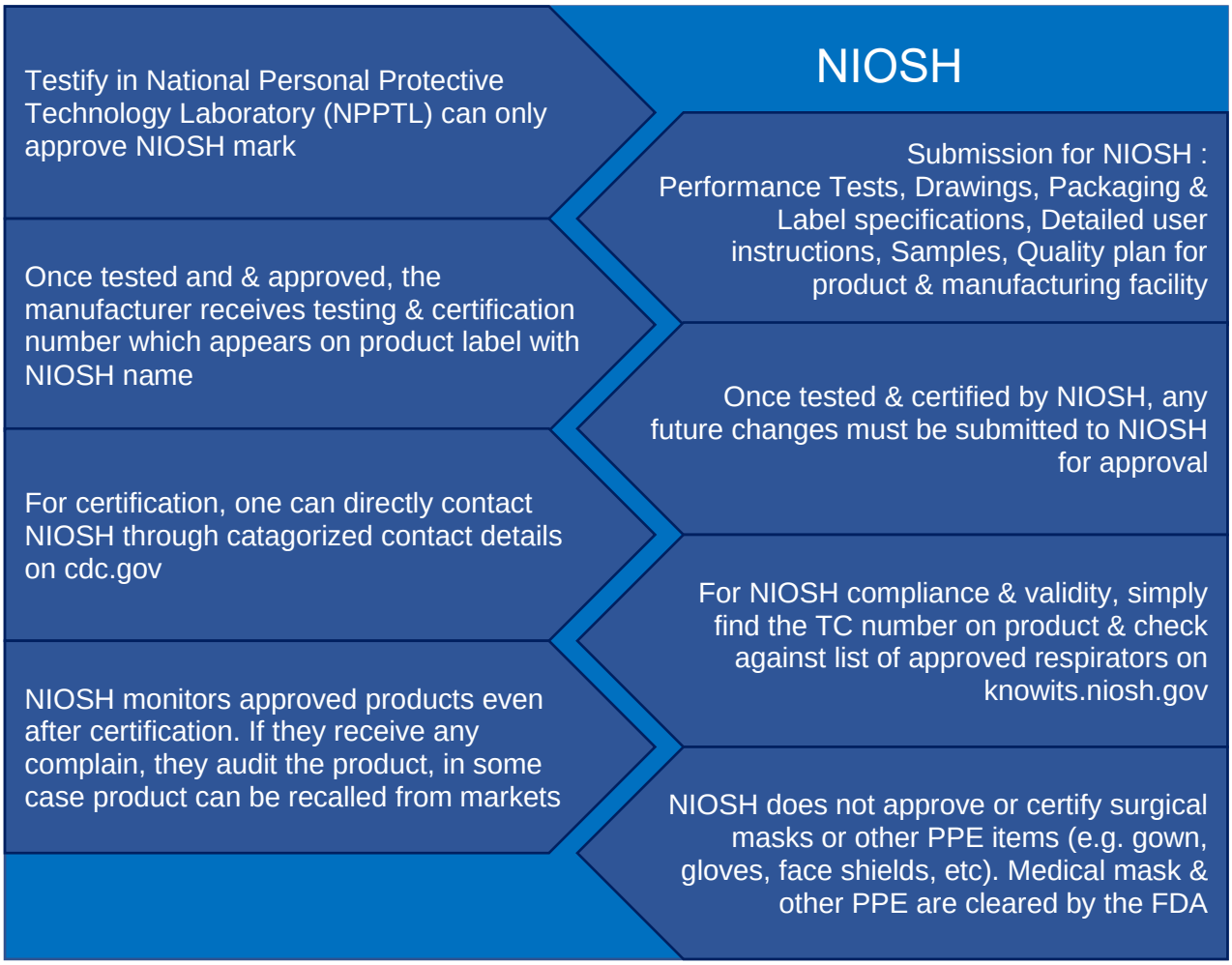


List of Third Party Review Organizations is posted and updated on https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfthirdparty/accredit.cfm

Recent List of FDA-Recognized Third Party Review Organization
AABB
Accelerated Device Approval Services, LLC
Biomarkers and Diagnostics Consulting, LLC
CENTER FOR MEASUREMENT STANDARDS OF INDUSTRIAL
COLA, Inc.
New York State Department of Health
REGULATORY TECHNOLOGY SERVICES, LLC
THIRD PARTY REVIEW GROUP, LLC

- Just for Information: FFR (Filtering Facepiece Respirators) have range of series depending on filter percentage like N95, N99, N100, R95, P95, P99, P100. Basic filtration difference is N series is to filter non-oily particles, R series is oil-resistant and P series is oil-proof masks with number assigned which indicates the accuracy of mask filter.

- NIOSH : National Institute for Occupational Safety and Health



How DS confirms Certified FDA Compliance?

- At Dragon Sourcing, we have identified the suppliers who are capable to supply to the US market
- As a part of RFI process, we request suppliers to send Certified FDA letter along with their product standards
- We verify them on fda.gov website where all the registered and approved manufacturers and suppliers are listed along with the products they have submitted and certified

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