

The Dun & Bradstreet D-U-N-S® Number & Public Health

The public health of America is a foremost priority – and FDA recently issued guidance formally recognizing the D-U-N-S Number as an acceptable unique facility identifier (UFI) for the Foreign Supplier Verification Programs (FSVP).

PROGRAM MISSION

The Food and Drug Administration's Food Safety Modernization Act (FSMA) aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it. Through this legislation, the agency intends to improve public health by adopting a modern, preventive, and risk-based approach to food safety regulation.

THE CHALLENGE

With approximately 200,000 domestic and foreign facilities required to register with the FDA, the agency's regulatory burden is set to grow amidst an expanding global supply chain. While the agency maintained a food facility registration database, the electronic system alone wasn't enough to support the agency's objective to assure the safety, efficacy and security of the nation's food supply. More importantly, due to limited resources, FDA is not able to inspect every registered facility with the frequency needed to ensure that the registration information for any specific facility is accurate at any specific time. Information may change between inspections, and inaccurate registration information could hinder FDA's ability to locate facilities for inspection.

THE SOLUTION

FDA updated registration regulations and sought out to better utilize limited inspection resources by improving the utility of the food facility registration database. As part of the registration process, the agency began requiring that food facilities submit a unique facility identifier (UFI), expanding FDA's facility verification capabilities and increasing the accuracy of the database. Given the successful use of the D-U-N-S Number for drug establishment registration, the agency issued guidance requesting facilities to use the D-U-N-S Number, which can be acquired at no cost, as an acceptable UFI.

"The more reliable information will better and more efficiently enable FDA to locate facilities during an outbreak of food borne illness, as well as locate facilities for inspection."

Food & Drug Administration
Preliminary Regulatory Impact Analysis
April 2015

The D-U-N-S Number supports FDA's efforts to implement Master Data Management (MDM) practices with the goal of establishing a single authoritative source for facility-identifying information. This also provides opportunities for linking information about each facility to the same unique identifier so that all information can be easily brought forward for quality control and regulatory decision-making.

Dun & Bradstreet ensures reliable facility identification and verification without relying solely on self-reported information which often contains errors and exposes the government to unauthorized system usage. Dun & Bradstreet's closed loop entity resolution process is augmented by global data stewards that independently verify certain facility information for the agency by conducting on-demand, on-site visits across the globe.

RESULTS AND ROI

FDA has significantly increased the speed to admissibility of appropriate products by increasing the number of verifications it conducts annually overseas. Outsourcing to Dun & Bradstreet has increased workload efficiency and savings for the FDA.

With the D-U-N-S Number underpinning FDA's Master Data Management initiative, and the majority of domestic and foreign food facilities already possessing the D-U-N-S Number, the agency has also made significant progress towards data harmonization and interoperability.

SOURCES

<https://www.gpo.gov/fdsys/pkg/FR-2016-07-14/pdf/2016-16531.pdf>

<https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM444325.pdf>

<https://www.fda.gov/downloads/aboutfda/transparency/transparencyreports/ucm394213.pdf>

<https://www.gao.gov/assets/690/681689.pdf>

<https://www.fda.gov/food/newsevents/constituentupdates/ucm549668.htm>

<https://www.gpo.gov/fdsys/pkg/FR-2016-07-14/pdf/2016-16531.pdf>

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