ION LABS	Standard Operating Procedure National Drug Code (NDC) Coding	SOP Number C-604	Revision 1
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1.0 Purpose

This procedure describes assignment and listing of a National Drug Product (NDC) code for Ion manufactured over-the-counter product. The NDC, or National Drug Code, is a unique 10 digit or 11 digit, 3-segment number, and a universal identifier for human drugs in the United States. The Drug Listing Act of 1972 requires registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. 21 CFR 207.35 defines the requirements of the foreign and domestic registration and listing for Human Drugs. Product and Facilities must also be registered with the State of Florida Department of Business and Professional Regulation.

2.0 Scope

This procedure is applicable for all over-the-counter (OTC) Ion manufactured product. All Ion manufactured OTC product produced for commercial distribution will be assigned a unique NDC number. All NDC submissions shall be established in the Structured Product Labeling format for OTC drugs. Ion as a contract manufacturer may only assign Ion's labeler code NDC listing number to Ion manufactured and distributed product.

3.0 Responsibility

3.1 The QA department is responsible for the overall coordination and administration of assigning, SPL submissions and maintaining a list of the product codes and packaging codes and assigning NDC numbers to Ion manufactured over-the-counter product. The QA department will maintain a master list of all assigned NDC numbers.

3.2 The Vice President of Regulatory Affairs and Quality Assurance is responsible for assuring that all provisions of this SOP are adhered to.

3.3 Research and Development is responsible for submitting Ion Lab over-the counter final approved drug formulas and raw material information to QA.

3.4 The Labeling Department is responsible for submitting Ion Lab manufactured finished product over-the-counter final approved labeling information to QA.

4.0 Definitions

4.1 **QA** – Quality Assurance

4.2 **NDC – National Drug Code** –Drugs are identified and reported using a unique, three – segment number, called the National Drug Code (NDC), which serves as the FDA's universal product identifier for drugs.

4.3 **cGMP** – current Good Manufacturing Practice

4.4 **DBPR** – State of Florida Department of Business and Professional Regulation -The Division of Drugs, Devices and Cosmetics safeguards the health, safety, and welfare of the citizens of the state of Florida from injury due to the use of adulterated, contaminated, misbranded drugs, drug ingredients and cosmetics by administering the provisions of the Florida Drug and Cosmetic Act (Chapter 499, F.S.). **SPL** – Structured Product Labeling – is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information and employs Extensible Markup Language (XML)

4.5 **Xforms** – Software to create SPL files based on XForms technology

4.6 **OTC** – Over-the counter

4.7 **CARES Act –FDA Law created to** aid response efforts and ease the economic impact of COVID-19. In addition to the COVID-19 response efforts, the CARES Act includes statutory provisions that reform and modernize the way OTC monograph drugs are regulated in the United States. The CARES Act also provides FDA the authority to assess and collect user fees dedicated to OTC monograph drug activities.

5.0 References

5.1 Section 510 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. §360))

5.2 The National Drug Code Directory, CDER, US FDA

5.3 Annex B – The Drug Listing Act of 1972 Information Bullet

5.4 National Drug Code Directory

5.5 CDER Direct / Xforms (Electronic registration and listing)

5.6 Structured Product Labeling Resources

6.0 Procedure

6.1 The process of requesting a NDC be assigned to Ion manufactured product may be initiated by forwarding to QA final approved labeling documents, formulation documents, and/or approved product profile documents.

6.2 The NDC code for Ion manufactured over-the-counter product shall consist of labeler code, product code and package code. It should not exceed 10 digits. Format of the NDC number shall be as follows:

6.2.1 69581-XXX-ZZ, i.e. Ion Lab's labeler code, XXX = product code, ZZ = package code.

6.3 The first set of numbers in the NDC identifies Ion Lab's labeler code (manufacturer, repackager, or distributor).

6.4 The second set of numbers is the product code, which identifies the specific strength, dosage form (i.e., capsule, tablet, liquid) and formulation of a drug for a specific company.

6.5 The third set of numbers is the package code, which identifies package size and type.

6.6 Ion Labs will submit to the FDA a Labeler Code Request, when necessary.

6.7 The FDA assigns a labeler code to Ion labs.

6.8 The QA Department will assign the product and package code and shall maintain a master list of assigned Ion Lab's NDC numbers in the QA files. Regulatory registrations and associated documents will be maintained by QA.

6.9 Ion Labs will assign a unique NDC number and list all over-the-counter drug products it produces for commercial distribution.

6.10 Ion Labs will utilize an outside 3rd party registration service to perform NDC number submissions in Structured Product Label format to the FDA to be filed in the national NDC directory, when appropriate.

6.10.1 Human drugs that are not in final marketed form are not included for view in the NDC directory, however are listed in the National Unfinished Drugs Database File.

6.11 Once Ion Lab's assigns an NDC code to one product it may not be later reassigned to a different product.

6.12 After the initial product listing, if there is a revision to the labeling, an update to the SPL will be initiated. The updated submission shall be maintained in the QA files.

6.13 If any changes occur in product characteristics, including a change in dosage form, active ingredient(s), strength or concentration, route of administration, or product name, a new NDC will be assigned to the new product version.

6.14 Different over-the-counter product formulations or different strengths of the same formulation will be assigned a different product code.

6.15 Any over-the counter drug product that shares the same formulation but has different product characteristics that clearly distinguish one product version from another will not share the same product code under the same labeler code and will be assigned different codes.

6.16 If Ion Labs no longer plans to manufacture an NDC listed product, Ion will also submit an "end of marketing date" submission and the end date will be the date of the last batch or lot of the over-the-counter drug manufactured.

6.17 OTC drug products also will be registered with the State of Florida (referencing the NDC Code). The appropriate information, labeling, and fee will be submitted appropriately with the DBPR.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	06/26/19	New procedure	N/A	L. Vick
1	08/05/22	Revise procedure to reference applicable regulation and guidance.	CC-22-0337	S. Millar