

## Inactive Ingredient Query Application

### Frequently Asked Questions Regarding the UNII

1. What is meant by the acronym "UNII"?  
The acronym "UNII" stands for "Unique Ingredient Identifier".
2. What is the purpose of the UNII?  
The UNII is a part of the joint USP/FDA Substance Registration System (SRS), which has been designed to support health information technology initiatives by providing unique identifiers for substances in drugs, biologics, foods, and devices based on molecular structure and/or descriptive information. The SRS is used to generate permanent, unique, unambiguous identifiers for substances in regulated products, such as ingredients in drug products.
3. Why is FDA displaying the UNII in association with inactive ingredients in this particular on-line query?  
The UNII is being displayed in association with inactive ingredients to facilitate Structured Product Labeling (SPL), which requires that a UNII be used for all ingredients, including inactive ingredients.
4. Why do some inactive ingredients not have a UNII?  
Not all inactive ingredients will receive a UNII. In order to receive a UNII, an ingredient must be a 'substance', which is defined as "Any physical material that has a discrete existence, irrespective of origin." Products will not be assigned a UNII. For example, "purified water" and "sterile water for injection" are considered products within the context of the SRS because something is done to the substance "water" in order to make it more useful. Proprietary ingredients, such as "OPADRY II 85F10919 BLUE", are considered products and will not be assigned a UNII.
5. Why can't other identifiers, such as the CAS number, be used instead of the UNII?  
Current substance identifiers that are used elsewhere in the federal government and in the private sector lack one or more of the characteristics important for supporting many of the health information technology initiatives.
6. If I need to request a UNII from FDA, how much will a UNII cost to obtain and to use?  
UNIIs can be freely obtained by contacting FDA through [SRS@cderr.fda.gov](mailto:SRS@cderr.fda.gov). Priority assignment of UNIIs may be given to those substances used in SPL. For some ingredients, the FDA may first need to convene its SRS Board before a UNII is assigned, and this process could delay the assignment of a UNII. FDA and USP reserve the right to assign UNIIs both where and when they deem necessary. UNIIs can be freely used world-wide, and do not require a license or licensing fee.
7. Where can I learn more information about the UNII?  
More information about the UNII and the SRS is available at <http://www.fda.gov/oc/datacouncil/SRS.htm>
8. Whom can I contact if I have questions about the UNII or the SRS that are not answered on the FDA website?  
All chemically-related questions about the UNII or the SRS that are not answered on the FDA website should be directed [SRS@cderr.fda.gov](mailto:SRS@cderr.fda.gov).