[^{18}F] NaF

FREQUENTLY ASKED QUESTIONS

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What is the status of sodium fluoride at the Cancer Imaging Program?

We have an established IND (9/2008) for sodium fluoride that we actively encourage investigators to cross-file on

- We freely provide an Investigator's Drug Brochure for anyone to use http://imaging.cancer.gov/programsandresources/Cancer-Tracer-Synthesis-Resources
- We have letters of authorization from some commercial suppliers to provide sodium fluoride under a Drug Master File (DMF)
- We encourage academic and pharmaceutical investigators to evaluate sodium fluoride for diagnosis and response to treatment of bone metastases

We filed an NDA that was approved in January 2011 so that others could file ANDA for this agent. The application was discontinued after approval, as NCI has no intent to market this drug, but its listing in the Orange Book permits anyone to file an Abbreviated New Drug Application (ANDA) for a generic version.

What is the Regulatory Status of Sodium Fluoride?

Sodium fluoride is currently an approved PET agent for bone scans. In the early 1970's, it was approved for marketing, but the NDA was withdrawn by the holder. It was not withdrawn for reasons of safety or efficacy, and in 2000 the FDA ruled that either an ANDA or NDA could be submitted for this drug (March 10, 2000. *Federal Register.*65:12999-13009). The NCI submitted an NDA for [^{18}F] sodium fluoride in December 2009 that was approved on January 26, 2011.

An IND Exemption from the FDA will permit you to make and use sodium fluoride for clinical trials and an ANDA filed with the FDA will permit you to make and use sodium fluoride for clinical care. Information on Positron Emission Tomography drugs is found here: **FDA PET Page.**

How can I use sodium fluoride in my clinical trial?

In general, in order to use sodium fluoride, you must hold an IND or have your basic science trial approved by your Institution's RDRC (Radioactive Drug Research Committee). In either case, you must have your trial approved by an Institutional Review Board (IRB).

How can I use sodium fluoride for clinical care?

In order to use sodium fluoride for clinical care, you must hold an NDA or an ANDA and prepare the drug under the PET cGMP regulations or purchase the drug from someone who has an NDA or an ANDA. Please refer to the FDA website for the most current information and links to applicable regulations and guidances for PET agents. **FDA PET Page.**

Can I make my own sodium fluoride?

If you have appropriate facilities (cyclotron, radiochemistry lab and personnel, capacity to manufacture PET agents for human use), you can make sodium fluoride. Your chemistry procedures must be acceptable to FDA for your IND or to the RDRC, and to the IRB. Since sodium fluoride has a USP monograph, you may be able to comply with it and meet FDA requirements. Please refer to the specific regulations and guidances regarding sodium fluoride at the FDA's website: **FDA PET Page.**

Can I buy sodium fluoride from someone to use in my trial?

Some commercial firms do provide sodium fluoride for research use. That material can be used in your clinical trial if the supplier has a Drug Master File (DMF) on file with the FDA for this agent, which would permit use of this material in your IND-approved trial with a letter of authorization or if you have a letter of authorization to our IND, which contains appropriate authorizations from three suppliers.

How can NCI help?

NCI can assist in two ways. NCI holds an IND for sodium fluoride that is based on DMF letters from commercial manufacturers and the FDA's determination in 2000 that there was adequate information on safety and efficacy to permit NDA filings. CIP will provide a Letter of Authorization (cross-file letter) to the FDA in conjunction with your IND that can simplify your IND application. This letter will substitute for the Pharmacology, Toxicology, Radiation Dosimetry and Previous Human Experience sections of the IND. An Investigator's Drug Brochure

for sodium fluoride for use in clinical trials is available on the Cancer Imaging Program (CIP) website.

http://imaging.cancer.gov/programsandresources/Cancer-Tracer-Synthesis-Resources

If you do purchase sodium fluoride from a company that holds a DMF, their Letter of Authorization will substitute for the Chemistry, Manufacturing, and Control section of your IND. If you purchase your sodium fluoride from an entity that has an NDA or filed ANDA, certification from the supplier as to that status should be sufficient.

For additional information

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