[^{18}F]FLUOROESTRADIOL, [^{18}F]FES

FREQUENTLY ASKED QUESTIONS

What is the status of FES at the Cancer Imaging Program?

We have an established IND (9/2007) for FES that we will permit investigators to cross- file on

- We provide manufacturing and quality control documentation to assist this effort https://imaging.cancer.gov/programs_resources/IND_regulatory_manufacturing.htm
- Since FES is now approved by FDA, it may be easier to source the drug from the commercial manufacturer and use the approved product labeling to file an IND.
- We encourage academic and pharmaceutical investigators to evaluate FES for indications other than the FDA approved indication, such as tumors besides breast cancer or for evaluation of therapies.

What is the Regulatory Status of FES?

- FES is currently an FDA approved PET agent (Cerriana™, Seimens PETNET). It is currently indicated for use with positron Emission Tomography (PET) imaging for detection of estrogen receptor (ER) positive lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer. NCCN Guidelines now recommend the use of FES PET for ER+ positive disease under certain circumstances during the systemic staging workup of patients with recurrent or metastatic breast cancer (MBC).
- In March 2023, Appropriate Use Criteria (AUC) for ER-targeted PET imaging was also published by the Society of Nuclear Medicine and Molecular Imaging (SNMMI)
- An IND Exemption from the FDA will permit you to make and use fluoroestradiol F18 for clinical trials for other indications and an ANDA filed with the FDA will permit you to make and use fluoroestradiol F18 for clinical care. Information on Positron Emission Tomography drugs is found here: IND information can be found here: Investigational New Drug Applications for Positron Emission Tomography (PET) Drugs | FDA
  PET drug information can be found here: **FDA PET Page.**

How can I use FES in my clinical trial?

In order to use FES for any indication other than that for the approved product, you must hold an IND and must have your trial approved by an Institutional Review Board (IRB).

Can I make my own FES?

If you have appropriate facilities (cyclotron, radiochemistry lab and personnel, capacity to manufacture PET agents for human use), you can make FES. Your chemistry procedures must be filed with, and acceptable to the FDA for your IND and to the IRB.

Can I buy FES from someone to use in my trial?

You can purchase FES from the commercial supplier, but will still need to have an IND if you intend to study any indication except the approved indication.

For additional information

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