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*APPLICATION NUMBER:*

**022494Orig1s000**

**PHARMACOLOGY REVIEW(S)**

## **Supervisory Pharmacologist Memo**

**NDA: 22-494**

**Drug: Sodium Fluoride [F-18] Injection**

**Sponsor: National Cancer Institute (NCI)**

**Date: May 26, 2009**

### **Recommendation for the approval of NDA 22-494; Sodium Fluoride [F-18] Injection**

From preclinical pharmacology and toxicology (P/T) perspective, NDA 22-494 can be approved. The sponsor did not submit any preclinical pharmacology and toxicology data for this 505(b)2 NDA application for Sodium Fluoride F-18 Injection. However, the sponsor referenced the March 10, 2000 Federal Register 65: 12999-13009. The March 2000 FR notice stated in part that, "FDA approved sodium fluoride F-18 injection (NDA 17-042) in 1972 as a bone imaging agent to define areas of altered osteogenic activity and further determined that sodium fluoride F 18injection was not withdrawn from sale for reasons of safety or effectiveness and is still a listed drug." The agency did not require additional P/T studies for Sodium Fluoride F-18 Injection applications. For this NDA, the PET Safety and Effectiveness Notice satisfy the information requirements for the nonclinical pharmacology and toxicology section.

From preclinical Pharmacology and Toxicology perspective NDA 22-494 can be approved.

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/s/

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5/26/2009 01:17:39 PM  
PHARMACOLOGIST