

Erratum to the FDA Briefing Document
Medical Imaging Drugs Advisory Committee Meeting
May 10, 2017

NDA 208630 for 5-Aminilevulinic Acid Hydrochloride (5-ALA) as an imaging agent to facilitate the real time detection and visualization of malignant tissue during glioma surgery

Erratum to the FDA Background Package

The section of the Briefing Document on page 19 of 24 titled **Fluorescence versus Complete Resection Correlations (additional analyses)** has been revised including **Table 12**.

The paragraph below the Table (six lines) has been deleted. The three lines preceding the Table have been replaced with a new paragraph above the Table. The Table has been revised.

The new section and the Table are presented here:

Fluorescence versus Complete Resection Correlations (additional analyses)

In the controlled study (ALS-3), in the 5-ALA FL Arm there were generally three biopsies per patient, with one of these being non-fluorescent. Table 12 reflects cross tabulations of the histology for the non-fluorescent biopsy with early post-surgery MRI status for patients in the 5-ALA arm and represents an attempt to correlate the two. As shown in the table, the available data from the 5-ALA FL arm do not reveal sufficient evidence that Completeness of Resection is associated with the histology status of the biopsied non-fluorescent tissue.

Table 12 Fluorescence versus Complete Resection Correlations

	Total MRIs N*	MRIs with Complete Resection n	Percentage
Non FL Biopsy is Histology Positive	106	38	36%
Non FL Biopsy is Histology Negative	29	12	41%

*: Two MRI are missing