



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Procedure Management & Business Support Division  
Scientific Committee Support Department

## Scientific recommendation on classification of advanced therapy medicinal products

Article 17 – Regulation (EC) No 1394/2007

**Disclaimer:** This document is a summary for public release of a scientific recommendation on classification of advanced therapy medicinal products. The original text adopted by the Committee for Advanced Therapies (CAT) has been redacted to delete commercially confidential information.

The present scientific recommendation refers exclusively to the case as presented to the European Medicines Agency (EMA) without prejudice to future evaluations by the Agency

### **Brief description (or name where available) of the active substance(s)**

Human retinal pigment epithelial cells derived from human embryonic stem cells.

### **Brief description of the finished product**

Suspension of human retinal pigment epithelial cells derived from human embryonic stem cells in cryopreservation medium.

### **Proposed indication**

Treatment of age-related macular degeneration and Stargardt's macular dystrophy.

### **EMA/CAT conclusion**

On the basis that:

- the cells are substantially manipulated so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved, and
- the product is administered to human beings with a view to regenerating, and replacing a human tissue,

the EMA/CAT considers that the Product falls within the definition of a Tissue Engineered Product.

