

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLORADO  
Magistrate Judge Boyd N. Boland

Civil Action No. 09-cv-00411-WYD-BNB

REGENERATIVE SCIENCES, INC.

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION;  
FRANK TORTI, M.D., in his Official Capacity as Commissioner of the United States Food and Drug Association;  
MARY A. MALARKEY, in her Official Capacity as Director of the Office of Compliance and Biologics Quality Center for Biologics Evaluation and Research;  
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES;  
CHARLES E. JOHNSON, in his Official Capacity as Acting Secretary of the United States Department of Health and Human Services;

Defendants.

---

**ORDER**

---

This matter arises on **Defendants' Motion to Exempt Case From Initial Disclosures, Discovery, and Expert Witness Testimony** [Doc. # 31, filed 5/20/2009] (the "Motion"), which is GRANTED.

In its Opposition Brief,<sup>1</sup> the plaintiff acknowledges that this is an action under the Administrative Procedures Act (the "APA") for review of agency action. Opposition Brief [Doc. # 38 at p.2](citing 5 U.S.C. § 706 as the section of the APA "which sets forth the scope of review available in cases filed pursuant to the APA"). Rule 26, Fed. R. Civ. P., and local rule of

---

<sup>1</sup>I refer to Plaintiff's Opposition to Defendants' Motion to Exempt Case From Initial Disclosures, Discovery, and Expert Witness Testimony [Doc. # 38, filed 6/5/2009] as the "Opposition Brief."

practice 16.2, D.C.COLO.LCivR, make clear that actions under the APA for review of agency action are exempt from the requirement of initial disclosures and from the entry of scheduling orders. In particular, Fed. R. Civ. P. 26(a)(1)(B)(i) provides that an action for review on an administrative record is “exempt from initial disclosure.” Similarly, D.C.COLO.LCivR 16.2 provides that “scheduling orders for discovery, joinder, and amendment of pleadings are unnecessary in . . . categories of proceedings listed in Fed. R. Civ. P. 26(a)(1)(B),” which includes actions, like this one, for review on administrative records.

Although judicial review under the APA generally is limited to the administrative record that was before the agency when it made its decision, Voyageurs Nat. Park Ass’n v. Norton, 381 F.3d 759, 766 (8th Cir. 2004), all parties concede that discovery may be allowed on limited issues. Motion at p.5 (noting that “the rule against discovery and/or going outside the administrative record assembled by the relevant agency in APA cases is not absolute”); Opposition Brief [Doc. # 38] at p.4 (stating that “courts often allow the administrative record to be supplemented through discovery in order to permit explanation or clarification of technical terms or subject matter involved in the agency action under review”). However, the party seeking discovery must “make a strong showing that the specific extra-record material” is warranted. Voyageurs, 381 F.3d at 766. No such showing has been made here, and it would be improper to require initial disclosures or to set a discovery schedule until the need for discovery has been established.

IT IS ORDERED that the Motion is GRANTED. My Order Setting Rule 16(b) Scheduling Conference and Rule 26(f) Planning Meeting [Doc. # 7] is VACATED.

IT IS FURTHER ORDERED that the parties shall file a status report within 10 days of any ruling on Defendants' Motion to Dismiss (etc.) [Doc. # 25, filed 4/29/2009] addressing what additional pretrial matters, if any, should be scheduled.

Dated June 10, 2009.

BY THE COURT:

s/ Boyd N. Boland  
United States Magistrate Judge