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7 QUEST NUTRITION, LLC and
8 GENERAL NUTRITION CENTERS, INC.

9 UNITED STATES DISTRICT COURT
10 FOR THE CENTRAL DISTRICT OF CALIFORNIA

11 DAVID TAKEDA, on behalf of
12 himself and all other persons similarly
13 situated,

14 Plaintiff,

15 v.

16 QUEST NUTRITION, LLC, a
17 California limited liability company;
18 and GENERAL NUTRITION
19 CENTERS, INC., a Delaware
20 corporation,

21 Defendants.

Case Number

2:13-cv-06656 PSG (JEMx)

Hon. Philip S. Gutierrez

**[PROPOSED] ORDER
GRANTING DEFENDANTS'
MOTION TO STAY THE
CASE PENDING FDA
ACTION UNDER THE
PRIMARY JURISDICTION
DOCTRINE (WHICH WAS
MADE AS A MOTION FOR
JUDGMENT ON THE
PLEADINGS)**

Date: December 1, 2014

Time: 1:30 p.m.

Courtroom: 880

The Hon. Philip S. Gutierrez

Action Filed: September 11, 2013

Trial Date: April 7, 2015

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1 Defendants Quest Nutrition, LLC (“Quest”) and General Nutrition Centers,
2 Inc. have moved for an order staying this case or dismissing it without prejudice
3 pending action by the U.S. Food and Drug Administration (“FDA”) under the
4 primary jurisdiction doctrine. The motion was made pursuant to Rule 12(c) of the
5 Federal Rules of Civil Procedure as a motion for judgment on the pleadings based
6 on the allegations in the Complaint (Docket No. 1) and FDA materials of which
7 the Court can take judicial notice under Rule 201 of the Federal Rules of
8 Evidence.

9 The Court has considered the parties’ papers and the oral argument of
10 counsel. For the reasons stated in the moving papers, the Court grants the motion
11 and orders that the case be stayed as specified herein.

12 Plaintiff David Takeda seeks to represent a nationwide class of consumers
13 who purchased Quest protein bars. His Complaint’s causes of action are based on
14 alleged mislabeling and marketing of Quest protein bars in terms of their fiber and
15 active carbohydrate contents due to the bars’ use of the fiber isomalto-
16 oligosaccharide (“IMO”). When the Complaint was filed in September 2013, the
17 FDA had no regulations defining dietary fiber.

18 On March 3, 2014, the FDA officially published in Volume 79 of the
19 Federal Register (at pages 11880 through 11987) a proposed Rule entitled “Food
20 Labeling: Revision of the Nutrition and Supplements Facts Labels” (to be codified
21 as an amended version of 21 CFR Part 101) whereby regulations for food labeling
22 are to be revised. Among many other things, the proposed Rule defines dietary
23 fiber for the first time, addresses how fiber should be measured, and mandates that
24 companies using isolated fibers (such as IMO) submit citizen’s petitions to the
25 FDA for it to determine if they are dietary fibers. The comment period closed on
26 August 1, 2014.

27 The Defendants submitted relevant portions of the proposed Rule to the
28 Court as part of a request for judicial notice. The Court grants the request and

1 takes judicial notice of the pertinent portions of the proposed Rule and an FDA
2 Notice about the comment period.

3 “The primary jurisdiction doctrine allows courts to stay proceedings or to
4 dismiss a complaint without prejudice pending the resolution of an issue within
5 the special competence of an administrative agency.” *Clark v. Time Warner*
6 *Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008).

7 “Although the question is a matter for the court’s discretion, courts in
8 considering the issue have traditionally employed such factors as (1) the need to
9 resolve an issue that (2) has been placed by Congress within the jurisdiction of an
10 administrative body having regulatory authority (3) pursuant to a statute that
11 subjects an industry or activity to a comprehensive regulatory authority that (4)
12 requires expertise or uniformity in administration.” *Syntek Semiconductor Co.,*
13 *Ltd. v. Microchip Technology Incorporated*, 307 F.3d 775, 781(9th Cir. 2002).

14 Courts are particularly likely to grant a stay or dismissal in situations where
15 an agency is actively considering the issues at the core of a case. *See, e.g., Clark*
16 *v. Time Warner*, 523 F.3d at 1115 (“the FCC’s Notice of Proposed Rulemaking
17 demonstrates that the agency is actively considering [the issues]”); *Greenfield v.*
18 *Yucatan Foods, L.P.*, __ F.Supp.2d __, 2014 WL 1891140 at *4 (S.D. Fla. May 7,
19 2014) (“courts [also] seem heavily influenced by a fifth factor: whether the FDA
20 [or another agency] has shown any interest in the issues presented by the
21 litigants”).

22 The circumstances present here militate heavily in favor of applying the
23 primary jurisdiction doctrine.

24 “Food labeling is within the special competence of the FDA [and] [t]he
25 FDCA imposes a comprehensive regulatory framework that requires uniformity in
26 administration.” *Figy v. Lifeway Foods*, 2014 WL 1779251 at *2 (N.D. Cal. May
27 5, 2014).

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1 The liability issues raised by Mr. Takeda in his Complaint are highly
2 technical in nature and concern dietary fiber measurement and labeling matters
3 that are not only within the FDA’s area of expertise but are the subject of ongoing
4 rulemaking activities by the FDA. Under the proposed Rule, all food
5 manufacturers (including Quest) who use isolated fiber (that is not in its intact,
6 original state) will have to go through a citizen’s petition process to get FDA
7 approval to label it as dietary fiber.

8 The Court will grant the motion and stay this case until after the proposed
9 Rule becomes final and after the FDA has responded to a citizen’s petition by
10 Quest to have IMO declared to be a dietary fiber. The case might end up being
11 mooted by the FDA actions but, if it is not, proceedings herein will continue after
12 the FDA has first weighed in on the fiber issues.

13 The Court HEREBY ORDERS that this action shall be stayed in its entirety
14 effective immediately. The parties are to file a joint status report on FDA
15 developments on or about _____, 2015.

16 IT IS SO ORDERED.

17 _____
18 Philip S. Gutierrez
19 U.S. District Court Judge
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