

115TH CONGRESS
1ST SESSION

H. R. 2009

To amend the Federal Food, Drug, and Cosmetic Act to provide clarity with respect to the regulation of diagnostic imaging devices intended for use with contrast agents.

IN THE HOUSE OF REPRESENTATIVES

APRIL 6, 2017

Mr. COSTELLO of Pennsylvania (for himself and Mr. PETERS) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide clarity with respect to the regulation of diagnostic imaging devices intended for use with contrast agents.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Fostering Innovation
5 in Medical Imaging Act of 2017”.

1 **SEC. 2. APPROVAL OF APPLICATIONS FOR CERTAIN DIAG-**
2 **NOSTIC MEDICAL IMAGING DEVICES.**

3 Section 520 of the Federal Food, Drug, and Cosmetic
4 Act (42 U.S.C. 360j) is amended by adding at the end
5 the following:

6 “Diagnostic Imaging Devices Intended for Use With
7 Contrast Agents

8 “(p)(1) The Secretary may, subject to the succeeding
9 provisions of this subsection, approve an application (or
10 supplement to such an application) submitted under sec-
11 tion 515 with respect to an applicable medical imaging de-
12 vice, or, in the case of an applicable medical imaging de-
13 vice for which a notification was submitted under section
14 510(k) (or a supplement to such a notification), may make
15 a substantial equivalence determination with respect to
16 such applicable medical imaging device, if the indications
17 and conditions of use proposed in such application or noti-
18 fication do not involve the use of a contrast agent—

19 “(A) in a concentration, rate of administration,
20 or route of administration that is different from
21 those described in the approved labeling of the con-
22 trast agent;

23 “(B) in a region, organ, or system of the body
24 that is different from those described in the ap-
25 proved labeling of the contrast agent, unless the Sec-
26 retary determines, based on information contained in

1 the application or notification involved, that the dif-
2 ference does not reduce the safety of the contrast
3 agent when used with the device;

4 “(C) in a new patient population for which the
5 contrast agent is determined by the Secretary to
6 pose an increased risk; or

7 “(D) in an imaging modality (such as an ultra-
8 sonic, ionizing radiation, or magnetic resonance
9 imagine modality) that is different from those de-
10 scribed in the approved labeling of the contrast
11 agent.

12 “(2) The agency center charged with premarket re-
13 view of devices shall have primary jurisdiction with respect
14 to the review of an application or notification described
15 in paragraph (1). In conducting such review, such agency
16 center may—

17 “(A) consult with the agency center charged
18 with the premarket review of drugs and biological
19 products; and

20 “(B) review information and data provided to
21 the Secretary by the sponsor of a contrast agent in
22 an application submitted under section 505, so long
23 as the sponsor of such contrast agent has provided
24 to the sponsor of the applicable medical imaging de-

1 vice that is the subject of such review a right of ref-
2 erence or use.

3 “(3) An application submitted under section 515 or
4 a notification submitted under section 510(k) with respect
5 to an applicable medical imaging device shall be subject
6 to the requirements of such respective section, and shall
7 not be subject to subsection (d) or (e) of section 505 (in-
8 cluding the substantial evidence standard specified in such
9 subsections).

10 “(4) An application submitted under section 515 or
11 a notification submitted under section 510(k) with respect
12 to an applicable medical imaging device intended for use
13 in conjunction with a contrast agent to which clause (ii)
14 or (iii) of section 505(c)(3)(E) applies shall refer to such
15 contrast agent by trade or brand name, rather than to
16 a class of drugs.

17 “(5) For purposes of this subsection and section
18 505(y)—

19 “(A) the term ‘applicable medical imaging de-
20 vice’ means a device intended to be used in conjunc-
21 tion with a contrast agent (or class of contrast
22 agents) for a use that is not described in the indica-
23 tions and usage section of the approved labeling of
24 such contrast agent (or the approved labeling of any

1 contrast agent in the same class as such contrast
2 agent); and

3 “(B) the term ‘contrast agent’ means a drug
4 that—

5 “(i) is a radioactive drug (as defined in
6 section 310.3(n) of title 21, Code of Federal
7 Regulations); or

8 “(ii)(I) is approved under section 505;

9 “(II) is intended for use in conjunction
10 with a diagnostic imaging device; and

11 “(III) achieves its intended use by enhance-
12 ing the contrast between a target tissue, struc-
13 ture, or fluid and the surrounding tissues or
14 structures within the body.”.

15 **SEC. 3. APPLICATIONS FOR APPROVAL OF CONTRAST**
16 **AGENTS INTENDED FOR USE WITH CERTAIN**
17 **DIAGNOSTIC MEDICAL IMAGING DEVICES.**

18 Section 505 of the Federal Food, Drug, and Cosmetic
19 Act (42 U.S.C. 355) is amended by adding at the end the
20 following:

21 “(y) CONTRAST AGENTS INTENDED FOR USE WITH
22 APPLICABLE MEDICAL IMAGING DEVICES.—

23 “(1) The sponsor of a contrast agent for which
24 an application has been approved under this section
25 may submit a supplement to the application seeking

1 approval for the use of the contrast agent for a new
2 contrast indication.

3 “(2) In reviewing a supplement submitted
4 under this subsection, the agency center charged
5 with the premarket review of drugs may—

6 “(A) consult with the center charged with
7 the premarket review of devices; and

8 “(B) review information and data sub-
9 mitted to the Secretary by the sponsor of an
10 applicable medical imaging device pursuant to
11 section 515 or 510(k), so long as the sponsor
12 of such applicable medical imaging device has
13 provided to the sponsor of the contrast agent a
14 right of reference or use.

15 “(3) For purposes of this subsection—

16 “(A) the term ‘new contrast indication’
17 means a use of a contrast agent that is de-
18 scribed in the approved labeling of an applicable
19 medical imaging device described in section
20 520(p), but that is not described in the indica-
21 tions and usage section of the approved labeling
22 of the contrast agent; and

1 “(B) the term ‘applicable medical imaging
2 device’ and ‘contrast agent’ have the meanings
3 given such terms in section 520(p).”.

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