SENATE BILL No. 415

DIGEST OF INTRODUCED BILL

Citations Affected: IC 24-5.

Essential off-patent or generic drugs. Prohibits a manufacturer or a wholesale distributor from engaging in price gouging in the sale of an essential off-patent or generic drug. Provides that the office of the secretary of family and social services (office) may provide to the attorney general a written notice of an increase in the price of an essential off-patent or generic drug if the price increase meets specified criteria. Provides that if the attorney general receives a notice of a price increase from the office, the attorney general may request the manufacturer identified in the notice to submit a statement that includes specified information about the increase. Provides that the attorney general has certain powers and duties with respect to price gouging in the sale of an essential off-patent or generic drug, including the power to bring a court action in Marion County if the attorney general determines that price gouging has occurred. Provides that if the court finds that a manufacturer or a wholesale distributor has engaged in price gouging, the court may issue an order to do one or more of the following: (1) Restrain or enjoin the violation. (2) Restore to any consumer (or third party payor) any money obtained by the manufacturer or wholesale distributor as a result of the violation. (3) Require a manufacturer that has engaged in price gouging to make the drug available to participants in certain state health plans or programs for a period of up to one year at the price at which the drug was available to the participants immediately before the effective date of the price increase constituting the violation. (4) Impose a civil penalty of up to \$10,000 for each violation. Provides that a person that engages in price gouging in the sale of an essential off-patent or generic drug (Continued next page)

Effective: July 1, 2019.

Breaux

January 14, 2019, read first time and referred to Committee on Health and Provider Services.



Digest Continued

commits a deceptive act that is subject to the remedies and penalties set forth in the statute concerning deceptive consumer sales. Makes a conforming amendment.



First Regular Session of the 121st General Assembly (2019)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in this style type, and deletions will appear in this style type.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or *this style type* reconciles conflicts between statutes enacted by the 2018 Regular and Special Session of the General Assembly.

SENATE BILL No. 415

A BILL FOR AN ACT to amend the Indiana Code concerning trade regulation.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 24-5-0.5-3, AS AMENDED BY P.L.170-2017
SECTION 2, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE
JULY 1, 2019]: Sec. 3. (a) A supplier may not commit an unfair
abusive, or deceptive act, omission, or practice in connection with a
consumer transaction. Such an act, omission, or practice by a supplied
is a violation of this chapter whether it occurs before, during, or after
the transaction. An act, omission, or practice prohibited by this section
includes both implicit and explicit misrepresentations.
(b) Without limiting the good of subgestion (c) the following esta

- (b) Without limiting the scope of subsection (a), the following acts, and the following representations as to the subject matter of a consumer transaction, made orally, in writing, or by electronic communication, by a supplier, are deceptive acts:
 - (1) That such subject of a consumer transaction has sponsorship, approval, performance, characteristics, accessories, uses, or benefits it does not have which the supplier knows or should



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1	reasonably know it does not have.
2	(2) That such subject of a consumer transaction is of a particular
3	standard, quality, grade, style, or model, if it is not and if the
4	supplier knows or should reasonably know that it is not.
5	(3) That such subject of a consumer transaction is new or unused,
6	if it is not and if the supplier knows or should reasonably know
7	that it is not.
8	(4) That such subject of a consumer transaction will be supplied
9	to the public in greater quantity than the supplier intends or
10	reasonably expects.
11	(5) That replacement or repair constituting the subject of a
12	consumer transaction is needed, if it is not and if the supplier
13	knows or should reasonably know that it is not.
14	(6) That a specific price advantage exists as to such subject of a
15	consumer transaction, if it does not and if the supplier knows or
16	should reasonably know that it does not.
17	(7) That the supplier has a sponsorship, approval, or affiliation in
18	such consumer transaction the supplier does not have, and which
19	the supplier knows or should reasonably know that the supplier
20	does not have.
21	(8) That such consumer transaction involves or does not involve
22	a warranty, a disclaimer of warranties, or other rights, remedies,
23	or obligations, if the representation is false and if the supplier
24	knows or should reasonably know that the representation is false.
25	(9) That the consumer will receive a rebate, discount, or other
26	benefit as an inducement for entering into a sale or lease in return
27	for giving the supplier the names of prospective consumers or
28	otherwise helping the supplier to enter into other consumer
29	transactions, if earning the benefit, rebate, or discount is
30	contingent upon the occurrence of an event subsequent to the time
31	the consumer agrees to the purchase or lease.
32	(10) That the supplier is able to deliver or complete the subject of
33	the consumer transaction within a stated period of time, when the
34	supplier knows or should reasonably know the supplier could not.
35	If no time period has been stated by the supplier, there is a
36	presumption that the supplier has represented that the supplier
37	will deliver or complete the subject of the consumer transaction
38	within a reasonable time, according to the course of dealing or the
39	usage of the trade.
40	(11) That the consumer will be able to purchase the subject of the

consumer transaction as advertised by the supplier, if the supplier

does not intend to sell it.



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1	(12) That the replacement or repair constituting the subject of a
2	consumer transaction can be made by the supplier for the estimate
3	the supplier gives a customer for the replacement or repair, if the
4	specified work is completed and:
5	(A) the cost exceeds the estimate by an amount equal to or
6	greater than ten percent (10%) of the estimate;
7	(B) the supplier did not obtain written permission from the
8	customer to authorize the supplier to complete the work even
9	if the cost would exceed the amounts specified in clause (A);
10	(C) the total cost for services and parts for a single transaction
11	is more than seven hundred fifty dollars (\$750); and
12	(D) the supplier knew or reasonably should have known that
13	the cost would exceed the estimate in the amounts specified in
14	clause (A).
15	(13) That the replacement or repair constituting the subject of a
16	consumer transaction is needed, and that the supplier disposes of
17	the part repaired or replaced earlier than seventy-two (72) hours
18	after both:
19	(A) the customer has been notified that the work has been
20	completed; and
21	(B) the part repaired or replaced has been made available for
22	examination upon the request of the customer.
23	(14) Engaging in the replacement or repair of the subject of a
24	consumer transaction if the consumer has not authorized the
25	replacement or repair, and if the supplier knows or should
26	reasonably know that it is not authorized.
27	(15) The act of misrepresenting the geographic location of the
28	supplier by listing an alternate business name or an assumed
29	business name (as described in IC 23-0.5-3-4) in a local telephone
30	directory if:
31	(A) the name misrepresents the supplier's geographic location;
32	(B) the listing fails to identify the locality and state of the
33	supplier's business;
34	(C) calls to the local telephone number are routinely forwarded
35	or otherwise transferred to a supplier's business location that
36	is outside the calling area covered by the local telephone
37	directory; and
38	(D) the supplier's business location is located in a county that
39	is not contiguous to a county in the calling area covered by the
40	local telephone directory.
41	(16) The act of listing an alternate business name or assumed
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business name (as described in IC 23-0.5-3-4) in a directory

1	assistance data base if:
2	(A) the name misrepresents the supplier's geographic location
3	(B) calls to the local telephone number are routinely forwarded
4	or otherwise transferred to a supplier's business location tha
5	is outside the local calling area; and
6	(C) the supplier's business location is located in a county tha
7	is not contiguous to a county in the local calling area.
8	(17) The violation by a supplier of IC 24-3-4 concerning
9	cigarettes for import or export.
10	(18) The act of a supplier in knowingly selling or reselling a
1	product to a consumer if the product has been recalled, whether
12	by the order of a court or a regulatory body, or voluntarily by the
13	manufacturer, distributor, or retailer, unless the product has beer
14	repaired or modified to correct the defect that was the subject of
15	the recall.
16	(19) The violation by a supplier of 47 U.S.C. 227, including any
17	rules or regulations issued under 47 U.S.C. 227.
18	(20) The violation by a supplier of the federal Fair Deb
19	Collection Practices Act (15 U.S.C. 1692 et seq.), including any
20	rules or regulations issued under the federal Fair Debt Collection
21	Practices Act (15 U.S.C. 1692 et seq.).
22	(21) A violation of IC 24-5-7 (concerning health spa services), as
23	set forth in IC 24-5-7-17.
24	(22) A violation of IC 24-5-8 (concerning business opportunity
25	transactions), as set forth in IC 24-5-8-20.
26	(23) A violation of IC 24-5-10 (concerning home consumer
27	transactions), as set forth in IC 24-5-10-18.
28	(24) A violation of IC 24-5-11 (concerning real property
29	improvement contracts), as set forth in IC 24-5-11-14.
30	(25) A violation of IC 24-5-12 (concerning telephone
31	solicitations), as set forth in IC 24-5-12-23.
32	(26) A violation of IC 24-5-13.5 (concerning buyback motor
33	vehicles), as set forth in IC 24-5-13.5-14.
34	(27) A violation of IC 24-5-14 (concerning automatic
35	dialing-announcing devices), as set forth in IC 24-5-14-13.
36	(28) A violation of IC 24-5-15 (concerning credit services
37	organizations), as set forth in IC 24-5-15-11.
38	(29) A violation of IC 24-5-16 (concerning unlawful motor
39	vehicle subleasing), as set forth in IC 24-5-16-18.
10	(30) A violation of IC 24-5-17 (concerning environmenta
1 1	marketing claims), as set forth in IC 24-5-17-14.
12	(31) A violation of IC 24-5-10 (concerning deceptive commercia



1	solicitation), as set forth in IC 24-5-19-11.
2	(32) A violation of IC 24-5-21 (concerning prescription drug
3	discount cards), as set forth in IC 24-5-21-7.
4	(33) A violation of IC 24-5-21.5 (concerning essential
5	off-patent or generic drugs), as set forth in IC 24-5-21.5-14(c).
6	(33) (34) A violation of IC 24-5-23.5-7 (concerning real estate
7	appraisals), as set forth in IC 24-5-23.5-9.
8	(34) (35) A violation of IC 24-5-26 (concerning identity theft), as
9	set forth in IC 24-5-26-3.
10	(35) (36) A violation of IC 24-5.5 (concerning mortgage rescue
11	fraud), as set forth in IC 24-5.5-6-1.
12	(36) (37) A violation of IC 24-8 (concerning promotional gifts
13	and contests), as set forth in IC 24-8-6-3.
14	(37) (38) A violation of IC 21-18.5-6 (concerning representations
15	made by a postsecondary credit bearing proprietary educational
16	institution), as set forth in IC 21-18.5-6-22.5.
17	(c) Any representations on or within a product or its packaging or
18	in advertising or promotional materials which would constitute a
19	deceptive act shall be the deceptive act both of the supplier who places
20	such representation thereon or therein, or who authored such materials,
21	and such other suppliers who shall state orally or in writing that such
22	representation is true if such other supplier shall know or have reason
23	to know that such representation was false.
24	(d) If a supplier shows by a preponderance of the evidence that an
25	act resulted from a bona fide error notwithstanding the maintenance of
26	procedures reasonably adopted to avoid the error, such act shall not be
27	deceptive within the meaning of this chapter.
28	(e) It shall be a defense to any action brought under this chapter that
29	the representation constituting an alleged deceptive act was one made
30	in good faith by the supplier without knowledge of its falsity and in
31	reliance upon the oral or written representations of the manufacturer,
32	the person from whom the supplier acquired the product, any testing
33	organization, or any other person provided that the source thereof is
34	disclosed to the consumer.
35	(f) For purposes of subsection (b)(12), a supplier that provides
36	estimates before performing repair or replacement work for a customer
37	shall give the customer a written estimate itemizing as closely as
38	possible the price for labor and parts necessary for the specific job
39	before commencing the work.
40	(g) For purposes of subsection (b)(15) and (b)(16), a telephone
41	company or other provider of a telephone directory or directory
42	assistance service or its officer or agent is immune from liability for
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1	publishing the listing of an alternate business name or assumed
2	business name of a supplier in its directory or directory assistance data
3	base unless the telephone company or other provider of a telephone
4	directory or directory assistance service is the same person as the
5	supplier who has committed the deceptive act.
6	(h) For purposes of subsection (b)(18), it is an affirmative defense
7	to any action brought under this chapter that the product has been
8	altered by a person other than the defendant to render the product
9	completely incapable of serving its original purpose.
10	SECTION 2. IC 24-5-21.5 IS ADDED TO THE INDIANA CODE
11	AS A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE
12	JULY 1, 2019]:
13	Chapter 21.5. Essential Off-Patent or Generic Drugs
14	Sec. 1. (a) As used in this chapter, "essential off-patent or
15	generic drug" means any prescription drug:
16	(1) for which all exclusive marketing rights, if any, granted
17	under:
18	(A) the federal Food, Drug, and Cosmetic Act (21 U.S.C.
19	301 et seq.);
20	(B) Section 351 of the federal Public Health Service Act (42
21	U.S.C. 262); or
22	(C) federal patent law;
23	have expired;
24	(2) that either:
25	(A) appears on the Model List of Essential Medicines most
26	recently adopted by the World Health Organization; or
27	(B) has been designated by the office of the secretary of
28	family and social services as an essential medicine because
29	of its efficacy in treating:
30	(i) a life-threatening health condition; or
31	(ii) a chronic health condition that substantially impairs
32	an individual's ability to engage in activities of daily
33	living;
34	(3) that is actively manufactured and marketed for sale in the
35	United States by three (3) or fewer manufacturers; and
36	(4) that is made available for sale in Indiana.
37	(b) The term includes any product:
38	(1) that includes a combination of a drug and a device used to
39	deliver the drug; and
10	(2) for which all exclusive marketing rights, if any, granted
1 1	under:
12	(A) the federal Food, Drug, and Cosmetic Act (21 U.S.C.



1	301 et seq.);
2	(B) Section 351 of the federal Public Health Service Act (42
3	U.S.C. 262); or
4	(C) federal patent law;
5	have expired.
6	Sec. 2. As used in this chapter, "health plan" means any of the
7	following:
8	(1) A state employee health plan (as defined in IC 5-10-8-6.7).
9	(2) A policy of accident and sickness insurance (as defined in
10	IC 27-8-5-1).
l 1	(3) An individual contract (as defined in IC 27-13-1-21) or a
12	group contract (as defined in IC 27-13-1-16).
13	Sec. 3. As used in this chapter, "health program" means any of
14	the following:
15	(1) The children's health insurance program (IC 12-17.6).
16	(2) Medicaid (IC 12-15).
17	(3) The healthy Indiana plan established by IC 12-15-44.5-3.
18	Sec. 4. As used in this chapter, "manufacturer", with respect to
19	a prescription drug, has the meaning set forth in 42 U.S.C.
20	1395w-3a.
21	Sec. 5. As used in this chapter, "price gouging" means an
22	unconscionable increase in the price of a prescription drug.
23	Sec. 6. As used in this chapter, "unconscionable increase", with
24	respect to an increase in the price of a prescription drug, means an
25	increase that:
26	(1) is excessive and not justified by the cost of:
27	(A) producing the drug; or
28	(B) appropriately expanding access to the drug to promote
29	public health; and
30	(2) results in an individual for whom the drug has been
31	prescribed having no meaningful choice about whether to
32	purchase the drug at an excessive price because of:
33	(A) the importance of the drug to the individual's health;
34	and
35	(B) insufficient competition in the marketplace for the
36	drug.
37	Sec. 7. As used in this chapter, "wholesale acquisition cost" has
38	the meaning set forth in 42 U.S.C. 1395w-3a.
39	Sec. 8. As used in this chapter, "wholesale distributor", with
10	respect to a prescription drug, has the meaning set forth in 21
11	U.S.C. 360eee.
12	Sec. 9. (a) A manufacturer or a wholesale distributor shall not



I	engage in price gouging in the sale of an essential off-patent or
2	generic drug.
3	(b) A wholesale distributor that increases the price of an
4	essential off-patent or generic drug does not violate subsection (a)
5	if the price increase is directly attributable to additional costs for
6	the drug imposed on the wholesale distributor by the manufacturer
7	of the drug.
8	Sec. 10. (a) The office of the secretary of family and social
9	services may provide to the office of the attorney general a written
10	notice of an increase in the price of an essential off-patent or
11	generic drug if:
12	(1) the price increase, by itself or in combination with other
13	price increases with respect to the essential off-patent or
14	generic drug:
15	(A) represents an increase of at least fifty percent (50%) in
16	the wholesale acquisition cost of the drug, as that cost
17	existed at any time during the twelve (12) month period
18	immediately preceding the effective date of the increase; or
19	(B) represents an increase of at least fifty percent (50%) in
20	the price paid by a health plan or health program for the
21	drug at any time during the twelve (12) month period
22	immediately preceding the effective date of the increase;
23	and
24	(2) one (1) of the following would apply after the effective date
25	of the price increase:
26	(A) A thirty (30) day supply of the maximum
27	recommended dosage of the drug for any indication,
28	according to the label for the drug approved under the
29	federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
30	seq.), would cost more than eighty dollars (\$80) at the
31	drug's wholesale acquisition cost.
32	(B) A full course of treatment with the drug, according to
33	the label for the drug approved under the federal Food,
34	Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), would cost
35	more than eighty dollars (\$80) at the drug's wholesale
36	acquisition cost.
37	(C) If the drug is made available to consumers only in
38	quantities that do not correspond to:
39	(i) a thirty (30) day supply;
40	(ii) a full course of treatment; or
41	(iii) a single dose;
42	obtaining a thirty (30) day supply or a full course of



1	treatment would cost more than eighty dollars (\$80) at the
2	drug's wholesale acquisition cost.
2 3	(b) A notice under subsection (a) must:
4	(1) identify the manufacturer of the essential off-patent or
5	generic drug;
6	(2) set forth with particularity the facts demonstrating that
7	the price increase represents an increase in an amount
8	described in subsection (a)(1)(A) or (a)(1)(B), or both,
9	including data on:
10	(A) the drug's wholesale acquisition cost; or
11	(B) the price paid by a health plan or health program for
12	the drug;
13	as applicable, during the twelve (12) month period
14	immediately preceding the effective date of the increase; and
15	(3) set forth with particularity facts demonstrating that the
16	price increase would result in a price exceeding eighty dollars
17	(\$80) at the drug's wholesale acquisition cost for one (1) of
18	the:
19	(A) quantities;
20	(B) treatment courses; or
21	(C) doses;
22	of the drug described in subsection (a)(2).
23	Sec. 11. (a) Subject to subsection (b), if the attorney general
24	receives a notice under section 10 of this chapter, the attorney
25	general may request the manufacturer identified in the notice to
26	submit, not later than forty-five (45) days after the date of the
27	attorney general's request, a written statement that includes the
28	following:
29	(1) An itemization of the components of the cost of producing
30	the drug.
31	(2) If applicable, a statement identifying the circumstances
32	and timing of any increase in:
33	(A) the costs of materials; or
34	(B) manufacturing costs;
35	that contributed to the manufacturer's increase in the price of
36	the essential off-patent or generic drug within the twelve (12)
37	month period immediately preceding the effective date of the
38	manufacturer's increase in the price of the essential off-patent
39	or generic drug.
40	(3) An explanation of:
41	(A) the circumstances and timing of any expenditures
42	made by the manufacturer to expand access to the drug;



1	and
2	(B) any known and quantifiable improvement in public
3	health associated with those expenditures.
4	(4) Any other information that the manufacturer determines
5	to be relevant to a determination of whether the
6	manufacturer's increase in the price of the essential off-patent
7	or generic drug constitutes a violation of section 9 of this
8	chapter.
9	(b) This section does not authorize the attorney general to
10	require a manufacturer to disclose confidential and proprietary
11	business plans or other confidential information without adequate
12	protection of the information. The attorney general shall exercise
13	all necessary caution to avoid disclosure of confidential
14	information supplied under this section.
15	Sec. 12. (a) The attorney general has the following powers and
16	duties with respect to price gouging in the sale of an essential
17	off-patent or generic drug:
18	(1) To investigate notices received under section 10 of this
19	chapter.
20	(2) To require a manufacturer or a wholesale distributor to
21	produce any records or other documents that may be relevant
22	to a determination of whether a violation of section 9 of this
23	chapter has occurred. However, this subdivision does not
24	authorize the attorney general to require a manufacturer or
25	a wholesale distributor to disclose confidential and
26	proprietary business plans or other confidential information
27	without adequate protection of the information. The attorney
28	general shall exercise all necessary caution to avoid disclosure
29	of confidential information supplied under this subdivision.
30	(3) To institute an action under section 13 of this chapter or
31	IC 24-5-0.5-4(c), or both.
32	(b) Upon petition by the attorney general, the circuit or superior
33	court of Marion County may issue an order to compel:
34	(1) a manufacturer to provide a statement requested by the
35	attorney general under section 11 of this chapter; or
36	(2) a manufacturer or a wholesale distributor to produce any
37	records or other documents requested by the attorney general
38	under subsection (a)(2);
39	subject to the attorney general's adequate protection of any
40	confidential and proprietary business plans or other confidential
41	information that may be included in the statement, records, or



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other documents requested.

1	Sec. 13. (a) Subject to subsection (c) and section 14(d) of this
2	chapter, if the attorney general determines, after an investigation
3	under section 12(a)(1) of this chapter, that a manufacturer or
4	wholesale distributor has engaged in price gouging in violation of
5	section 9 of this chapter, the attorney general may bring an action
6	in the circuit or superior court of Marion County seeking one (1)
7	or more of the following:
8	(1) Injunctive relief, as appropriate.
9	(2) Restitution for victims of price gouging.
10	(3) The imposition of a civil penalty.
11	(b) After considering the evidence in an action filed under
12	subsection (a), if the court finds that a manufacturer or a wholesale
13	distributor has engaged in price gouging in violation of section 9 of
14	this chapter, the court may issue an order to do any one (1) or
15	more of the following:
16	(1) Restrain or enjoin the violation of section 9 of this chapter.
17	(2) Restore to any consumer, including a third party payor,
18	any money obtained by the manufacturer or wholesale
19	distributor as a result of the violation of section 9 of this
20	chapter.
21	(3) Require a manufacturer that has engaged in price gouging
22	in the sale of an essential off-patent or generic drug in
23	violation of section 9 of this chapter to make the drug
24	available to participants in any:
25	(A) health plan; or
26	(B) health program;
27	for a period of up to one (1) year at the price at which the
28	drug was made available to the participants immediately
29	before the effective date of the price increase constituting the
30	violation of section 9 of this chapter.
31	(4) Impose a civil penalty of up to ten thousand dollars
32	(\$10,000) for each violation of section 9 of this chapter.
33	(c) The attorney general may not bring an action under
34	subsection (a) unless the attorney general has first provided the
35	manufacturer or wholesale distributor an opportunity to meet with
36	the attorney general to offer a justification for the increase in the
37	price of the essential off-patent or generic drug at issue.
38	Sec. 14. (a) The requirements set forth in this chapter are not
39	exclusive and do not relieve a person from complying with any
40	other applicable:
41	(1) state or federal statute, rule, or regulation; or
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(2) order of:

(A) a court;
(B) an administrative agency; or
(C) a regulatory body;
with jurisdiction.
(b) The remedies and penalties set forth in this chapter are
cumulative and in addition to any other applicable remedies and
penalties.
(c) Subject to subsection (d), a person that violates section 9 of
this chapter commits a deceptive act that is subject to the remedies
and penalties set forth in IC 24-5-0.5. An action by the attorney
general under IC 24-5-0.5-4(c) for a violation of section 9 of this
chapter may be brought in the circuit or superior court of Marion
County.
(d) An action brought under:
(1) this chapter; or
(2) IC 24-5-0.5;
that alleges price gouging in the sale of an essential off-patent or
generic drug in violation of section 9 of this chapter must be
brought within two (2) years after the effective date of the price
increase that is alleged to constitute price gouging.

