

holidays, submit to the responsible Flight Standards office a complete report of the operations of the aircraft involved in the deviation, including a description of the deviation and the reasons for it.

(e) *Expiration.* This SFAR will remain in effect until October 27, 2020. The FAA may amend, rescind, or extend this SFAR as necessary.

(f) *Definitions.* (1) The Simferopol FIR (UKFV) is defined as that airspace from the surface to unlimited within the following lateral limits:

465800N 0360000E–463500N
0364200E–
463424N 0372206E–452700N
0364100E–
452242N 0364100E–451824N
0363524E–
451442N 0363542E–451218N
0363200E–
450418N 0363418E–445612N
0363636E–
443100N 0364000E–424400N
0361600E–
424700N 0340000E–424800N
0320000E–
424800N 0310000E–424800N
0304500E–
434100N 0303200E–441000N
0302512E–
441500N 0302400E–444600N
0300900E–
445447N 0300448E–445230N
0302130E–
445848N 0303342E–451530N
0310642E–
452436N 0312500E–453828N
0315311E–
454436N 0320548E–455442N
0322700E–
460730N 0325430E–464600N
0325300E–
474400N 0330300E–472700N
0344800E–
470630N 0355500E–465800N 0360000E

(2) The Dnipropetrovsk FIR (UKDV) is defined as that airspace from the surface to unlimited within the following lateral limits:

511400N 0342700E–504942N
0341300E–
502043N 0335720E–501246N
0335307E–
491848N 0333700E–485700N
0332200E–
484118N 0324431E–483620N
0324010E–
483128N 0323605E–482300N
0323900E–
480730N 0325324E–474600N
0325000E–
474400N 0330300E–472700N
0344800E–
470630N 0355500E–465800N
0360000E–
463500N 0364200E–463424N
0372206E–

463930N 0372518E–464700N
0373000E–
465900N 0382000E–470642N
0381324E–
then along state boundary until point/–
511400N 0342700.

Issued in Washington, DC, under the authority of 49 U.S.C. 106(f) and (g), 40101(d)(1), 40105(b)(1)(A), and 44701(a)(5), on October 15, 2018.

Daniel K. Elwell,

Acting Administrator.

[FR Doc. 2018–22853 Filed 10–18–18; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 227 and 230

[Release No. 33–10567]

Regulation Crowdfunding and Regulation A Relief and Assistance for Victims of Hurricane Michael

AGENCY: Securities and Exchange Commission.

ACTION: Interim final temporary rule.

SUMMARY: We are adopting interim final temporary rules for issuers subject to reporting obligations pursuant to Regulation Crowdfunding and Regulation A in order to address the needs of companies directly or indirectly affected by Hurricane Michael. The temporary rules extend the filing deadlines for specified reports and forms due pursuant to Regulation Crowdfunding and Regulation A for certain issuers.

DATES: These rules are effective from October 19, 2018 through November 23, 2018, except that amendatory instruction 1 revising the authority citation of part 227 is effective October 19, 2018.

FOR FURTHER INFORMATION CONTACT: Jennifer Zepalka, Office Chief, or Amy Reischauer, Special Counsel, Office of Small Business Policy, Division of Corporation Finance, at (202) 551–3460, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–3628.

SUPPLEMENTARY INFORMATION: We are adopting amendments to 17 CFR 227.202 (“Rule 202”) of Regulation Crowdfunding¹ under the Securities Act of 1933 (the “Securities Act”)² and 17 CFR 230.257 (“Rule 257”) of Regulation A³ under the Securities Act as interim final temporary rules.

¹ 17 CFR 227 *et seq.*

² 15 U.S.C. 77a *et seq.*

³ 17 CFR 230.251 through 230.263.

I. Introduction

On October 10, 2018, Hurricane Michael made landfall on the Florida Panhandle. The storm and subsequent flooding have displaced individuals and businesses and disrupted communications and transportation across the affected region. We are adopting these interim final temporary rules to address the needs of companies directly or indirectly affected by Hurricane Michael or its aftermath that are subject to reporting obligations pursuant to Regulation Crowdfunding or Regulation A.

Section 28 of the Securities Act provides that the Commission may, by rule or regulation, “conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision or provisions of this title or of any rule or regulation issued under this title, to the extent that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.”⁴

II. Temporary Relief From Filing Requirements for Issuers Subject to the Reporting Obligations of Regulation Crowdfunding or Regulation A

The lack of communications, transportation, electricity, facilities, and available staff and professional advisors as a result of Hurricane Michael could hamper the efforts of companies with reporting obligations to meet their filing deadlines pursuant to Regulation Crowdfunding or Regulation A. At the same time, investors have an interest in the timely availability of required information about these companies. While the Commission believes that the temporary relief from filing requirements provided by the amendments to Rule 202 of Regulation Crowdfunding⁵ and Rule 257 of Regulation A⁶ is both necessary in the public interest and consistent with the protection of investors, we remind companies that are the subject of the relief provided in these interim final temporary rules to continue to evaluate their obligations to make materially accurate and complete disclosures in accordance with the anti-fraud provisions of the federal securities laws.

Accordingly, pursuant to Section 28 of the Securities Act, we are adopting interim final temporary rules providing that an issuer subject to the reporting

⁴ 15 U.S.C. 77z–3.

⁵ See Rule 202(c) of Regulation Crowdfunding, 17 CFR 227.202(c).

⁶ See Rule 257(f) of Regulation A, 17 CFR 230.257(f).

requirements of either Regulation Crowdfunding or Regulation A is exempt from any requirement to file specified reports or forms with the Commission where the conditions below are satisfied:

(a) The issuer is not able to meet a filing deadline due to Hurricane Michael or its aftermath;

(b) The issuer files with the Commission, on or before November 23, 2018, the report or form required to be filed pursuant to either Regulation Crowdfunding or Regulation A during the period from and including October 10, 2018 to and including November 21, 2018; and

(c) In any such report or form, the issuer discloses that it is relying on the interim final temporary rules and states the reasons why, in good faith, it could not file such report or form on a timely basis.

For Regulation Crowdfunding, the relief includes annual reports on Form C-AR, progress updates on Form C-U, and termination of reporting on Form C-TR. For Regulation A, the relief includes post-qualification amendments required at least every 12 months after the qualification date to include updated financial statements, annual reports on Form 1-K, semi-annual reports on Form 1-SA, special financial reports on Forms 1-K or 1-SA, current reports on Form 1-U, and exit reports on Form 1-Z.

III. Economic Analysis

Regulation Crowdfunding and Regulation A permit offers and sales of securities without registration under the Securities Act, subject to certain limitations and conditions, including compliance with ongoing reporting requirements. Based on staff analysis, between June 19, 2015 (the effective date of the most recent Regulation A amendments⁷) and September 30, 2018, approximately 244 filers had Regulation A offering statements qualified by the Commission, excluding withdrawn offerings. Approximately 1,067 issuers initiated Regulation Crowdfunding offerings with Form C filings between May 16, 2016 and September 30, 2018, excluding issuers that have withdrawn offerings.⁸ Approximately 41 registered intermediaries, including 32 registered funding portals and 9 registered broker-dealers, have participated in Regulation Crowdfunding offerings with Form C

filings between May 16, 2016 and September 30, 2018, excluding withdrawn offerings.

We lack the data to estimate the number of investors in Regulation A or Regulation Crowdfunding offerings that could be affected if issuers rely on the relief provided by the interim final temporary rules, because information on the number of investors is generally not required to be disclosed in periodic or current reports required under Regulation A or in periodic reports or progress updates required under Regulation Crowdfunding.⁹

We are mindful of the costs and benefits of the interim final temporary rules.¹⁰ We believe the interim final temporary rules will benefit issuers that have an obligation to file specified reports with the Commission pursuant to either Regulation Crowdfunding or Regulation A and have been adversely affected by Hurricane Michael or its aftermath by permitting them to take additional time to meet their reporting obligations. We expect the relief provided by the interim final temporary rules will benefit issuers that, absent the relief, would not be able to avail themselves of the exemption from registration under Regulation Crowdfunding or Regulation A because the timely filing of required reports is a condition to the exemptions. In the absence of this relief, issuers could incur prohibitively high costs in an attempt to meet filing deadlines given the lack of communications, transportation, electricity, facilities, and available staff and professional advisors.

The requirement for an issuer to disclose that it is relying on Rule 202(c) of Regulation Crowdfunding or Rule 257(f) of Regulation A and to state the reasons why, in good faith, it could not file a report or form on a timely basis may impose minimal additional costs on issuers availing themselves of this relief. However, we believe that these minimal costs are justified in light of the significant negative implications of not being able to rely on the exemption and the prohibitively high costs an issuer may incur in attempting to file in a timely manner.

We also acknowledge that there may be costs imposed on investors, intermediaries, and other market

participants due to delayed access to information about offerings conducted in reliance on Regulation A and Regulation Crowdfunding. Generally, reporting requirements strengthen investor protection and decrease the extent of information asymmetries between issuers and investors. Ongoing reporting provides investors with periodically updated information, allowing them to assess investment opportunities based on the information provided and their level of risk tolerance, resulting in better informed investment decisions and improved allocative efficiency. Given that the interim final temporary rules allow for delayed reporting for a limited time period and only under specified conditions, we do not believe such costs will be significant.

The interim final temporary rules will not substantially affect competition or capital formation. We acknowledge the possibility that the interim final temporary rules may have a minor impact on efficiency. On the one hand, as noted above, the delay in reporting could marginally affect allocative efficiency to the extent that it allows information asymmetries between investors and issuers to persist for the length of time of the delay. On the other hand, we expect efficiency gains to the extent that the interim final temporary rules allow issuers to continue to rely on either of the exemptions from registration that would not be available if one of the required reports that is a condition to the exemptions was not filed in a timely manner, or to the extent the issuers are able to avoid paying a premium to service providers in an attempt to file in a timely manner by delaying reporting during the specified relief period.

As an alternative to the relief specified in the interim final temporary rules, we could have considered a longer or shorter relief period. While a shorter period would have reduced the costs to investors of asymmetric information, it would also reduce the benefits of the interim final temporary rules to issuers. Similarly, a longer period would increase the costs to investors. We believe that the approximately six-week delay in the interim final temporary rules is appropriate given the potential impact Hurricane Michael or its aftermath could have on the efforts of companies to meet filing deadlines pursuant to Regulation Crowdfunding and Regulation A.

IV. Procedural and Other Matters

The Administrative Procedure Act (“APA”) generally requires an agency to

⁷ SEC Rel. No. 33-9741 (Mar. 25, 2015) [80 FR 21806 (Apr. 20, 2015)].

⁸ These figures overstate the number of issuers with obligations to file annual reports under Regulation Crowdfunding, because they do not exclude issuers that have failed to raise the target amount or have exited the reporting regime.

⁹ Regulation A issuers that file Form 1-Z to suspend reporting are required to disclose the number of shareholders of record.

¹⁰ Section 2(b) of the Securities Act [15 U.S.C. 77b(b)] requires the Commission, when engaging in rulemaking where it is required to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation.

publish notice of a rulemaking in the **Federal Register** and provide an opportunity for public comment. This requirement does not apply, however, if the agency “for good cause finds . . . that notice and public procedure are impracticable, unnecessary, or contrary to the public interest.”¹¹ The APA also generally requires that an agency publish an adopted rule in the **Federal Register** at least 30 days before it becomes effective. This requirement does not apply, however, if the agency finds good cause for making the rule effective sooner.¹²

Given the temporary nature of the relief contemplated by the interim final temporary rules and the significant and immediate impact of Hurricane Michael and its aftermath on issuers in affected areas, as discussed above, the Commission finds that good cause exists to dispense with notice and comment as impracticable and unnecessary, and to act immediately to amend Rule 202 of Regulation Crowdfunding and Rule 257 of Regulation A.¹³ Further, the interim final temporary rules will not affect the burden or cost estimates associated with existing collections of information under Regulation Crowdfunding and Regulation A for purposes of the Paperwork Reduction Act of 1995.¹⁴

V. Statutory Basis and Text of Amendments

We are adopting amendments to Rule 202 of Regulation Crowdfunding and Rule 257 of Regulation A under the authority set forth in the Securities Act (15 U.S.C. 77a *et seq.*), particularly, Section 28 thereof.

List of Subjects

17 CFR Part 227

Crowdfunding, Funding portals, Intermediaries, Reporting and recordkeeping requirements, Securities.

17 CFR Part 230

Reporting and recordkeeping requirements, Securities.

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 227—REGULATION CROWDFUNDING, GENERAL RULES AND REGULATIONS

■ 1. The authority citation for part 227 is revised to read as follows:

Authority: 15 U.S.C. 77d, 77d–1, 77s, 77z–3, 78c, 78o, 78q, 78w, 78mm, and Pub. L. 112–106, secs. 301–305, 126 Stat. 306 (2012).

■ 2. Amend § 227.202 by adding paragraph (d) to read as follows:

§ 227.202 Ongoing reporting requirements.

* * * * *

(d) *Temporary relief from certain reporting requirements.* (1) An issuer that is not able to meet a filing deadline for any report or form required to be filed by this section, 17 CFR 227.203(a)(3), or 17 CFR 227.203(b) during the period from and including October 10, 2018 to and including November 21, 2018 due to Hurricane Michael and its aftermath shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before November 23, 2018.

(2) In any report or form filed pursuant to paragraph (d)(1) of this section, the issuer must disclose that it is relying on this paragraph (d) and state the reasons why, in good faith, it could not file such report or form on a timely basis.

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

■ 3. The authority citation for part 230 continues to read in part as follows:

Authority: 15 U.S.C. 77b, 77b note, 77c, 77d, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77sss, 78c, 78d, 78j, 78l, 78m, 78n, 78o, 78o–7 note, 78t, 78w, 78ll(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, and Pub. L. 112–106, sec. 201(a), sec. 401, 126 Stat. 313 (2012), unless otherwise noted.

* * * * *

■ 4. Amend § 230.257 by adding paragraph (g) to read as follows:

§ 230.257 Periodic and current reporting; exit report.

(g) *Temporary relief from ongoing reporting requirements.* (1) An issuer that is not able to meet a filing deadline for any report or form required to be filed by 17 CFR 230.252(f)(2)(i) or this section during the period from and including October 10, 2018 to and including November 21, 2018 due to Hurricane Michael and its aftermath

shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before November 23, 2018.

(2) In any report or form filed pursuant to paragraph (g)(1) of this section, the issuer must disclose that it is relying on this paragraph (g) and state the reasons why, in good faith, it could not file such report or form on a timely basis.

By the Commission.

Dated: October 16, 2018.

Brent J. Fields,

Secretary.

[FR Doc. 2018–22930 Filed 10–17–18; 4:15 pm]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. FDA–2018–N–3684]

Medical Devices; Anesthesiology Devices; Classification of the Positive Airway Pressure Delivery System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the positive airway pressure delivery system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the positive airway pressure delivery system’s classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 19, 2018. The classification was applicable on June 5, 2018.

FOR FURTHER INFORMATION CONTACT: Deepika Arora Lakhani, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2543, Silver Spring, MD 20993–0002, 301–796–4042, Deepika.Lakhani@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

¹¹ 5 U.S.C. 553(b)(3)(B).

¹² 5 U.S.C. 553(d)(3).

¹³ This finding also satisfies the requirements of 5 U.S.C. 808(2), allowing the interim final temporary rules to become effective notwithstanding the requirement of 5 U.S.C. 801 (if a federal agency finds that notice and public comment are impractical, unnecessary or contrary to the public interest, a rule shall take effect at such time as the federal agency promulgating the rule determines). The interim final temporary rules also do not require analysis under the Regulatory Flexibility Act. See 5 U.S.C. 604(a) (requiring a final regulatory flexibility analysis only for rules required by the APA or other law to undergo notice and comment).

¹⁴ 44 U.S.C. 3501 *et seq.*