safety and effectiveness. In addition, they recognize that results of clinical studies supporting general recognition of safety and effectiveness will in most instances be contained in the published scientific literature. Such publications seldom, if ever, contain the same level of detail as the clinical study reports and data tabulations submitted in support of new drug applications, but it has long been understood that they may form the basis for determinations of general recognition of safety and effectiveness under the OTC monograph system. Finally, the regulations clearly permit determinations of general recognition of safety and effectiveness to be based on sources of information other than the published scientific literature, including, for example, unpublished data from studies carried out by federal government agencies or other competent bodies which are made available to the FDA in the process of administering the OTC monograph system. It is our intent that the FDA should continue to apply these standards in making determinations of general recognition of safety and effectiveness under the monograph reform legislation.

STATEMENT OF INTENT AS TO MINOR CHANGES PROVISION

Under current law, dosage forms for monograph OTC drugs have largely been limited to the technology in use in 1972, when the OTC Drug Review began. The only mechanism for introducing truly innovative dosage forms has been through the new drug application (NDA) process, which entails disproportionate costs and delays. This has proved to be a significant hurdle to use of new technologies that could offer consumers greater convenience and choice in OTC drug products.

The legislation creates two new procedures for introducing innovative dosage forms for monograph OTC drugs that would not otherwise be permitted under subsection (b).

First, sponsors may initiate proceedings for the issuance of administrative orders under subsection (c) to provide for use of novel dosage forms.

Second, in appropriate cases, sponsors may make minor changes in dosage forms without prior approval from FDA, using the procedure in subsection (d). The sponsor must maintain information necessary to demonstrate that the change will not affect the safety or effectiveness of the drug or materially affect the extent of absorption or other exposure to the drug in comparison to a suitable reference product. The sponsor must also submit updated drug listing information to FDA within 30 days of introducing the new product to the market. FDA will have the right to demand access to the relevant files, and there will be a quick and simple procedure to resolve any disagreement between FDA and the sponsor as to the adequacy of the data supporting the change. Before the subsection (d) procedure takes effect, FDA must issue administrative orders setting out the type of information required to support minor changes in dosage forms. In issuing those orders, FDA will take account of standard procedures and practices for evaluating the quality of drug products, including applicable provisions of the United States Pharmacopeia/National Formulary, as well as special needs of populations, including children.

The procedures in subsections (c) and (d) will only be required for changes that would not otherwise be permitted under subsection (b). Thus, changes in excipients or other inactive ingredients and similar aspects of formulation of monograph OTC drug products will be permitted without prior approval provided they are fully consistent with requirements of applicable monographs or administrative orders and with general requirements for monograph OTC drugs, including, among other things, requirements for the use of suitable inactive ingredients which are safe in the amounts administered and do not interfere with the effectiveness of the preparation or with suitable tests or assays. When such changes are made, sponsors will be required to submit updated drug listing information to FDA within 30 days of introducing a product to the market.

USP AND INTERNATIONAL CONFERENCE ON HARMONIZATION AS SOURCES FOR STANDARDS DESCRIPTIONS IN MINOR CHANGES ADMINISTRATIVE ORDER WITH GUIDANCES BY ROUTE OF ADMINISTRATION

An important objective of this legislation is to create procedures that will promote innovation by permitting manufacturers to introduce certain new and improved dosage forms for nonprescription monograph drugs without the need for prior FDA approval. Manufacturers will be required to maintain files containing data showing that such changes will not affect the safety or effectiveness of their products and provide those files to FDA on request. The bill directs FDA to issue administrative orders and guidances describing the types of changes that can be made without prior approval and the data that manufacturers should have on file. Subsection (d)(3)(B) requires that, in issuing such orders and guidances, FDA should take account of relevant public standards for evaluating the quality of drug products. Examples of the standards that FDA should take into account include the monographs and other provisions of United States Pharmacopeia/National Formulary and guidelines issued by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). FDA is a major stakeholder in both organizations, and it is appropriate that any administrative orders it adopts should take account of relevant requirements issued by them.

LABELING CONSIDERATIONS UNDER MINOR CHANGES PROVISION

This bill establishes procedures under which FDA can issue binding administrative orders setting forth the requirements under which nonprescription drugs will be regarded as generally recognized as safe and effective and may be lawfully marketed without an approved new drug application. It is intended that these orders will be similar in content to the monographs that FDA has issued under the current procedures of the Over-the-Counter (OTC) Drug Review. That is, they will contain provisions concerning active ingredients, dosages and dosage forms, and instructions for safe use of the products to which they apply and, where appropriate, other conditions required to assure safety and effectiveness. Nonprescription drugs marketed under such orders must also comply with general requirements of the Federal Food, Drug, and Cosmetic Act and applicable FDA regulations, including general requirements for labeling and quality. As is true under the current regulatory system, labels and labeling for nonprescription drugs may contain additional information, including brand names, promotional statements, and other information, provided that any such information is truthful and non-misleading.

Mr. HILL of Arkansas. Mr. Speaker, the health and economic crisis caused by COVID–19 is unprecedented in our lifetimes. We are seeing the number of cases rise throughout the country, including in my home state of Arkansas. After being in nearly constant communication with the Arkansas Governor's office, hospitals, first responders, and business leaders in Arkansas, relief from the federal government is needed to help fight this virus and help keep our businesses from going under. It is for these reasons that if a roll call vote is called for the vote on the Coronavirus Aid, Relief, and Economic Security Act, I will vote yes.

Mr. FLORES. Mr. Speaker, I rise to state that if there is a recorded vote, I would vote: ''yea'' on H.R. 748, Coronavirus Aid, Relief, and Economic Security Act, as amended.

As referenced in my earlier remarks during the H.R. 748 debate, this legislation takes vital steps to send cash to struggling Texas families, provide economic relief for small businesses and working Americans, and give our healthcare providers more of the resources they need.

The SPEAKER pro tempore. All time for debate has expired.

Pursuant to House Resolution 911, the previous question is ordered on the motion.

The question is on adoption of the motion.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

RECORDED VOTE

Mr. MASSIE. Mr. Speaker, I demand a recorded vote.

A recorded vote was refused.

Mr. MASSIE. Mr. Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

The SPEAKER pro tempore. The Chair will count for a quorum.

A quorum is present.

The motion to concur was agreed to.

A motion to reconsider was laid on the table.

ADJOURNMENT

The SPEAKER pro tempore. Pursuant to section 7(b) of House Resolution 891, the House stands adjourned until 3 p.m. on Tuesday, March 31, 2020.

Thereupon (at 1 o'clock and 27 minutes p.m.), under its previous order, the House adjourned until Tuesday, March 31, 2020, at 3 p.m.

EXECUTIVE COMMUNICATIONS, ETC.

Under clause 2 of rule XIV, executive communications were taken from the Speaker's table and referred as follows:

4184. A letter from the Director, Regulations Management Division, Department of Agriculture, transmitting the Department's final rule — Special Servicing of Telecommunications Programs Loans for Financially Distressed Borrowers (RIN: 0572-AC41) received March 17, 2020, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Agriculture.

4185. A letter from the Deputy General Counsel, Office of Elementary and Secondary