in the **Federal Register** of May 6, 2024. The amendment is being made to reflect a change in the **ADDRESSES** portion of the document and to reflect a change in the *Procedure* portion. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, email: *TPSAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 6, 2024 (89 FR 37231), FDA announced that a meeting of the Tobacco Products Scientific Advisory Committee would be held on June 26, 2024, from 9 a.m. to 4:30 p.m. EST. On page 37232, in the first column, the last paragraph of the **ADDRESSES** portion of the document is changed to read as follows:

For those unable to attend in person, the meeting will also be webcast and will be available at the following link: *https://fda.zoomgov.com/j/1604157441?pwd=YkVzZ28vNHQrVXh3ZlhrTmlHaFVzZz09;* Passcode: H*a5nF.

In addition, on page 37232 in the middle column under *Procedure,* the oral presentations or open public hearing time is now scheduled to start at 11:30 a.m. and end at 12:30 p.m. EST on June 26, 2024.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and 21 CFR part 14, relating to the advisory committees.

Dated: June 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–12784 Filed 6–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2583]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Drug Compounding, Repackaging, and Related Activities Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with Agency guidance documents pertaining to pharmacies, outsourcing facilities, and other entities with regard to human drug compounding, repackaging, and related activities.

DATES: Either electronic or written comments on the collection of information must be submitted by August 12, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 12, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–2583 for ''Human Drug Compounding, Repackaging, and Related Activities Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit

both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Human Drug Compounding, Repackaging, and Related Activities Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0858—Extension

I. Background

This information collection helps support implementation of sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a and 21 U.S.C. 353b), which govern compounding by pharmacies, outsourcing facilities, and other entities. Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Although compounded drugs can serve an important medical need for certain patients, they also present risks to patients. FDA's compounding program aims to protect patients from unsafe, ineffective, and poor-quality compounded drugs, while preserving access to lawfully marketed compounded drugs for patients who have a medical need for them. Respondents to the information collection are pharmacies, outsourcing facilities, and other entities.

II. Guidances

To assist respondents in complying with statutory requirements, we have issued the following topic-specific guidance documents:

TABLE 1—PUBLISHED GUIDANCE DOCUMENTS REGARDING SECTIONS 503A AND 503B OF THE FD&C ACT

Title	Notice of availability publication date
Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities (Radiopharmaceutical Compounding and Repackaging Guidance) (available at *https://www.fda.gov/media/102615/download*).	September 26, 2018 (83 FR 48633).
Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities (Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance) (available at *https://www.fda.gov/media/102637/download*).	September 26, 2018 (83 FR 48630).
Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities (Repackaging Guidance) (available at *https://www.fda.gov/media/90978/download*).	January 13, 2017 (82 FR 4343).
Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application (Biological Products Guidance) (available at *https://www.fda.gov/media/90986/download*).	January 19, 2018 (83 FR 2787).

These guidance documents were issued consistent with FDA's good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time. The guidance documents communicate FDA's current thinking on the respective topics and include information collection that may result in expenditures of time and effort by respondents. In FDA's notices of availability for the guidance documents, we also solicited public comment under the PRA on the information collection provisions. FDA has developed and maintains a searchable guidance database available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Guidance documents covered by this information collection may be found by choosing ''Center for Drug Evaluation and Research'' from among the FDA Organizations, and by selecting the term

''Compounding'' from among the possible Filters.[1]

A. Radiopharmaceutical Compounding and Repackaging Guidance

Because Congress explicitly excluded radiopharmaceuticals from section 503A of the FD&C Act (see section 503A(d)(2)), compounded radiopharmaceuticals are not eligible for the exemptions under section 503A from section 505 of the FD&C Act (21 U.S.C. 355) (concerning new drug approval requirements), section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) (concerning labeling with adequate directions for use), and section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)B)) (concerning current good manufacturing practice (CGMP) requirements). In addition, the FD&C Act does not provide an exemption for repackaged radiopharmaceuticals. The guidance describes the conditions under which FDA does not intend to take action for violations of sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act when a State-licensed nuclear pharmacy, Federal facility, or other facility that is not an outsourcing facility and that holds a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State compounds or repackages radiopharmaceuticals for human use. The guidance explains that one condition is that the compounded radiopharmaceutical is not essentially a copy of an approved radiopharmaceutical. As described in the guidance, FDA does not intend to consider a compounded radiopharmaceutical to be essentially a copy if, among other reasons, there is a change between the compounded radiopharmaceutical and the approved radiopharmaceutical that produces a clinical difference for an identified individual patient, as determined by the prescribing practitioner and documented in writing on the prescription or order. In addition, FDA does not intend to consider a compounded radiopharmaceutical to be essentially a copy if the FDA-approved radiopharmaceutical is on FDA's drug shortage list (see section 506E of the FD&C Act (21 U.S.C. 356e)) at the time of compounding and distribution. If the facility compounded a drug that is identical or nearly identical to an approved drug product that appeared on FDA's drug shortage list, the facility should maintain documentation (*e.g.,* a notation on the order for the compounded drug) regarding the status of the drug on FDA's drug shortage list at the time of compounding, distribution, and dispensing.

B. Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance

In contrast to section 503A, section 503B of the FD&C Act does not exclude radiopharmaceuticals. Therefore, FDA's overall policies regarding section 503B of the FD&C Act apply to the compounding of radiopharmaceuticals. However, we have developed specific policies that apply only to the compounding of radiopharmaceuticals by outsourcing facilities using bulk drug substances and to the compounding of radiopharmaceuticals by outsourcing facilities that are essentially copies of approved drugs when such compounding is limited to minor deviations, as that term is defined in the guidance. FDA issued this guidance in part to describe the conditions under which the Agency does not generally intend to take action for violations of sections 505 and 502(f)(1) of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals for human use.

As discussed in the guidance, one condition is that if a radiopharmaceutical is repackaged by an outsourcing facility, the label on the immediate container (primary packaging, *e.g.,* the syringe) of the repackaged product includes certain information.

C. Repackaging Guidance

The guidance describes the conditions under which FDA does not intend to take action for violations of sections 505 (concerning new drug applications), 502(f)(1) (concerning labeling with adequate directions for use), 582 ((21 U.S.C. 360eee–1) concerning drug supply chain security requirements), and (where specified in the guidance) 501(a)(2)(B) of the FD&C Act (concerning CGMPs), when a State-licensed pharmacy, Federal facility, or outsourcing facility repackages certain prescription drugs. One condition discussed in the guidance is that if a drug is repackaged by an outsourcing facility, the label on the immediate container (primary packaging, *e.g.,* the syringe) of the repackaged product includes certain information described in the guidance.

Conditions discussed in the guidance include that if a drug is repackaged by an outsourcing facility, the label on the immediate container (primary packaging, *e.g.,* the syringe) and on the container from which the individual units are removed for administration (secondary packaging, *e.g.,* the bag, box, or other package in which the repackaged products are distributed) of the repackaged product include certain information described in the guidance.

D. Biological Products Guidance

Certain licensed biological products may sometimes be mixed, diluted, or repackaged in a way not described in the approved labeling for the product to meet the needs of a specific patient. As described in the guidance, biological products subject to licensure under section 351 of the Public Health Service (PHS) Act (42 U.S.C. 262) are not eligible for the statutory exemptions available to certain compounded drugs under sections 503A and 503B of the FD&C Act. In addition, a biological product that is mixed, diluted, or repackaged outside the scope of an approved biologics license application (BLA) is considered an unlicensed biological product under section 351 of the PHS Act.

This guidance document describes several conditions under which FDA does not intend to take action for violations of section 351 of the PHS Act and sections 502(f)(1), 582, and (where specified) 501(a)(2)(B) of the FD&C Act, when a State-licensed pharmacy, a Federal facility, or an outsourcing facility dilutes, mixes, or repackages certain biological products outside the scope of an approved BLA.

One condition discussed in the guidance is that if the labeling for the licensed biological product includes storage instructions, handling instructions, or both (*e.g.,* protect from light, do not freeze, keep at specified storage temperature), the labeling for the biological product that is mixed, diluted, or repackaged specifies the same storage conditions. Another condition described in the guidance is that, if the biological product is mixed, diluted, or repackaged by an outsourcing facility, the label on the immediate container (primary packaging, *e.g.,* the syringe) of the mixed, diluted, or repackaged product includes certain information described in the guidance. In addition, the guidance communicates that as a condition for biological products mixed, diluted, or repackaged by an outsourcing facility that, if the immediate product label is too small to bear the active and inactive ingredients, such information is included on the label of the container from which the

[1] Guidance documents applicable to animal drug compounding regulated by the Center for Veterinary Medicine would also be returned if no FDA Organization is selected; this information collection covers only those compounding guidance documents issued by the Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research.

individual units are removed for administration (secondary packaging, *e.g.,* the bag, box, or other package in which the mixed, diluted, or repackaged biological products are distributed).

The guidance also communicates FDA's thinking about the condition for biological products mixed, diluted, or repackaged by an outsourcing facility that the label on the container from which the individual units are removed for administration include directions for use. These directions include, as appropriate, the dosage and administration and the following information to facilitate adverse event reporting: *https://www.fda.gov/medwatch* and 1–800–FDA–1088.

Finally, another condition described in the guidance is that outsourcing facilities maintain records of the testing performed in accordance with ''Appendix A—Assigning a BUD for Repackaged Biological Products Based on Stability Testing'' of the guidance for biological products repackaged by outsourcing facilities for which the beyond use date (BUD) is established based on a stability program conducted in accordance with Appendix A.

Section III.C of the guidance, ''Licensed Allergenic Extracts for Subcutaneous Immunotherapy,'' discusses the preparation of prescription sets (*i.e.,* licensed allergenic extracts that are mixed and diluted to provide subcutaneous immunotherapy to an individual patient) by a physician, a State-licensed pharmacy, a Federal facility, or an outsourcing facility. Another condition described in the guidance is that if the prescription set is prepared by an outsourcing facility, the label of the container from which the individual units of the prescription set are removed for administration (secondary packaging) includes the following information to facilitate adverse event reporting: *https://www.fda.gov/medwatch* and 1–800–FDA–1088. Each prescription set prepared by an outsourcing facility is also accompanied by instructions for use.

III. Electronic Product Reporting to FDA

Outsourcing facilities submit their initial and biannual product reports identifying drug products repackaged during the previous 6-month period to FDA via the Agency's electronic Drug Registration and Listing System (eDRLS) as explained in the Radiopharmaceutical Compounding and Repackaging Guidance by Outsourcing Facilities and the Repackaging Guidance. Also, we expect to receive no waiver requests from the electronic submission process for initial product reports and semiannual reports.

We estimate the burden of this information collection as follows:

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Recommended activity; guidance section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Radiopharmaceutical Compounding and Repackaging Guidance					
Consultation between the compounder and prescriber and the notation on the prescription or order documenting the prescriber's determination of clinical difference (section III.A of the Radiopharmaceutical Compounding and Repackaging Guidance).	10	25	250	.05 (3 minutes)	12.5
Biological Products Guidance					
Maintaining records of testing performed in accordance with Appendix A of the Biological Products Guidance (section III.B of the Biological Products Guidance).	5	30	150	0.083 (5 minutes)	12.5
Total	15	.....	400	.....	25

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE [1] [2]

Recommended activity; guidance section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance					
Designing, testing, and producing each label on immediate containers, packages, and/or outer containers (section III.B of the Radiopharmaceutical Compounding and Repackaging Guidance by Outsourcing Facilities).	2	5	10	0.5 (30 minutes) ...	5
Repackaging Guidance					
Designing, testing, and producing each label on immediate containers, packages, and/or outer containers (section III.A of the Repackaging Guidance).	6	36	216	1	216
Biological Products Guidance					
Designing, testing, and producing the label, container, packages, and/or outer containers for each mixed, diluted, or repackaged biological product (section III.B of the Biological Products Guidance).	15	5	75	0.5 (30 minutes) ...	37.5
Designing, testing, and producing each label on immediate containers, packages, and/or outer containers for each licensed allergenic extract (section III.C of the Biological Products Guidance).	5	300	1,500	0.5 (30 minutes) ...	750
Total	28	.....	1,801	.....	1,009

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals may not sum due to rounding.

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

Recommended activity; guidance section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance					
Biannual product reports identifying drug products repackaged by the outsourcing facility during the previous 6-month period (section III.B of the Radiopharmaceutical Compounding and Repackaging Guidance by Outsourcing Facilities)	2	2	4	3	12
Repackaging Guidance					
Biannual product reports identifying drug products repackaged by the outsourcing facility during the previous 6-month period (section III.A of the Repackaging Guidance)	6	2	12	3	36
Total	8		16		48

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

For purposes of our analysis, we characterize the burden associated with the time and effort expended on the information collection recommendations discussed in the respective guidance documents as either recordkeeping, reporting, or third-party disclosure activities. We reconfigured the original table by splitting it into three tables to better differentiate between the estimated annual recordkeeping burden, the estimated annual reporting burden, and the estimated annual third-party disclosure burden. At the same time, our findings show that compliance with recordkeeping requirements applicable to compounded and repackaged drug products is standard practice in the compounding and selling of these drug products under States' pharmacy laws and other State laws governing recordkeeping by healthcare professionals and healthcare facilities. Therefore, we excluded from our estimate recordkeeping practices discussed in the respective guidance documents we consider usual and customary. We invite comment on this assumption.

For the Repackaging Guidance, to correct a clerical error, we have adjusted the number of disclosures per respondent from 21 to 36 because each respondent is estimated to average 6 different products and average 6 different strengths, which requires 36 (6 × 6) unique labels per respondent. The initial narrative reflected that each product would come in 6 different strengths and thus require 6 unique labels, but due to a clerical error, this information was not correctly included in the table. We also adjusted the number of respondents to 6 to match the number of respondents designing, testing, and producing labels. In addition, we adjusted the total number of disclosures per respondent to 2 given the biannual reporting requirement.

For the Radiopharmaceutical Compounding and Repackaging by Outsourcing Facilities Guidance, a row for biannual product reporting was added to capture product reporting that was inadvertently omitted.

Our estimated burden for the information collection reflects constant respondent numbers. The original numbers were based on the information the program received from product reporting data. We do not have a mechanism in place to determine whether or not these numbers have fluctuated upward or downward; however, based on analogous observations of industry through program experience (some product reports), we believe these numbers are constant. Repackagers who are also registered as outsourcing facilities (OF) are not entity types that are individually regulated as repackagers. They are subsumed in the OF entity type and not easily distinguishable. They may or may not report their repackaging operations.

We are updating the information collection to include burden attendant to reporting and disclosure recommendations found in the Agency guidance documents that was inadvertently omitted in the original information collection due to clerical errors. The burden estimate is adjusted to reflect a resulting increase of 114 hours and 94 responses annually.

Dated: June 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–12783 Filed 6–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4806]

Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under the Federal Food, Drug, and Cosmetic Act; Notice; Request for Information and Comments; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing this request for information to better understand the status of trading partners' interoperable systems and processes for enhanced drug distribution security as required by the Food, Drug and Cosmetic Act (FD&C Act). FDA is reopening the comment period for the notice, published in the **Federal Register** of November 20, 2023, establishing a public docket and requesting information and comments, to allow interested persons additional time to comment.

DATES: FDA is reopening the comment period on the notice published November 20, 2023 (88 FR 80726). Either electronic or written comments must be submitted by September 12, 2024.

ADDRESSES: You may submit information and comments at any time as follows:

Electronic Submissions

Submit electronic comments in the following way: